UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

DONALD KAPPS, M.D.,

Plaintiff,

v.

BIOSENSE WEBSTER, INC., a Johnson & Johnson Company, and ASCENT HEALTHCARE SOLUTIONS, INC.,

Defendants.

Case No. 09-CV-1039 (PJS/JSM)

ORDER

Tara D. Sutton and Kelly M. McLain, ROBINS, KAPLAN, MILLER & CIRESI L.L.P., for plaintiff.

Tracy J. Van Steenburgh and Dana M. Lenahan, NILAN JOHNSON LEWIS PA, for defendant Biosense Webster, Inc.

Blake W. Duerre, Lindsay G. Arthur, Jr., Beth A. Jenson Prouty, and Michelle M. Carter, ARTHUR, CHAPMAN, KETTERING, SMETAK & PIKALA, P.A., for defendant Ascent Healthcare Solutions, Inc.

In this lawsuit, plaintiff Donald Kapps, M.D., seeks to recover for injuries he suffered after the tip of a catheter made by defendant Biosense Webster, Inc. ("Biosense") and reprocessed by defendant Ascent Healthcare Solutions, Inc. ("Ascent")[1] broke off in his heart during a medical procedure at the Mayo Clinic. Kapps filed a motion for summary judgment, Biosense filed a motion for summary judgment, Ascent filed two motions for summary

[1]Ascent either acquired or was formerly known as Alliance Medical Corporation. *See, e.g.*, McLain Aff. [Docket No. 93] Ex. 24. Ascent has since become Stryker Sustainability Solutions. *See* Stryker Sustainability Solutions, About Stryker Sustainability Solutions, http://www.ascenths.com/about (last visited Sept. 20, 2011).

judgment, and the parties together filed the equivalent of eight motions to exclude expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The Court heard arguments on these motions at a day-long hearing on March 17, 2011.

The Court ruled on many of the parties' motions from the bench. Specifically, the Court denied Kapps's motions for summary judgment and granted in part and denied in part Kapps's motions to exclude the testimony of various defense experts. The Court also granted in part and denied in part Ascent's motion to exclude the testimony of David G. Benditt, M.D., one of Kapps's expert witnesses. Those rulings were reduced to writing the following day. Order Mar. 18, 2011 [Docket No. 121].

The Court took under advisement the motions of Biosense and Ascent to exclude the testimony of Kapps's primary expert witness, Bruce H. Barkalow, Ph.D. The Court also took under advisement the motions of Biosense and Ascent for summary judgment. Biosense's and Ascent's motions raised a host of difficult issues — including legal issues on which there appears to be little helpful authority.

The Court now rules on Biosense's and Ascent's *Daubert* and summary-judgment motions. For the reasons that follow, the Court excludes Barkalow's testimony with respect to Biosense and grants summary judgment to Biosense. With respect to Ascent, the Court excludes Barkalow's testimony only to the extent that it relates to approval by the United States Food and Drug Administration ("FDA") of Ascent's reprocessing procedures, and the Court grants in (small) part and denies in (large) part Ascent's motions for summary judgment.

The Court also denies Kapps's motion for leave to amend his complaint to add a claim for punitive damages. Kapps initially submitted his motion to Magistrate Judge Janie S.

Mayeron, but in light of the pendency of the parties' *Daubert* and summary-judgment motions, Judge Mayeron referred the motion to the undersigned.

I. BACKGROUND

A. Facts

1. Kapps's Injuries[2]

Kapps suffers from atrial fibrillation, a condition in which the heart's rhythm is fast and irregular.[3] In June 2005, during a procedure at the Mayo Clinic to treat the condition, a Lasso catheter made by Biosense and reprocessed by Ascent was manipulated inside Kapps's heart by Dr. Ming Wong, a visiting fellow who was supervised by Dr. Douglas L. Packer. The Lasso catheter is a "mapping" catheter whose function is to measure the conductivity of areas within the heart before and after treatment of those areas with an ablation catheter. The Lasso takes its name from the circular open loop (or "lasso") that forms the catheter's tip.

While Wong was manipulating the Lasso catheter inside the left atrium of Kapps's heart, the lasso portion of the catheter's tip flipped across the mitral valve into Kapps's left ventricle and became entrapped in the mitral valve and its supporting structures or "chordae." Packer then

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[2]The basic facts surrounding Kapps's injuries are undisputed. Dr. Douglas L. Packer, the supervising electrophysiologist, described in detail during his deposition the procedure that resulted in Kapps's injuries. Packer Dep. at 32-55, 87-98, 101-04. The complete transcript of Packer's October 30, 2009 deposition is in the record as McLain Aff. [Docket No. 93] Ex. 4. Fragments of the transcript are found in at least two other places. McLain Aff. [Docket No. 52] Ex. 8; Lenahan Aff. [Docket No. 78] Ex. A.

[3]"In atrial fibrillation, the electrical impulse of the heart is not regular. The atria contract very quickly and not in a regular pattern. This makes the ventricles beat abnormally, leading to an irregular (and usually fast) pulse. As a result, the heart cannot pump as much blood as the body needs." U.S. Nat'l Library of Medicine & NIH, Medline Plus — Medical Encyclopedia, "Atrial fibrillation/flutter," http://www.nlm.nih.gov/medlineplus/ency/article/000184.htm (last visited Sept. 20, 2011).

took over for Wong and attempted to extricate the catheter by rotating it. The lasso portion snapped off and remained entangled in Kapps's mitral valve and chordae; Packer withdrew the rest of the catheter. Various other doctors assisted Packer in attempting to snare the detached loop with devices introduced through a catheter, and eventually they succeeded in removing the loop.

In the meantime, however, Kapps's blood pressure dropped, and he experienced bleeding into the pericardium (the sac surrounding the heart). His mitral valve was also damaged. To treat his pericardial bleeding and the damage to his mitral valve, Kapps underwent open-heart surgery, and his mitral valve was replaced with a porcine prosthesis. He has suffered various health problems as a result of the surgery.

2. The Lasso Catheter

The Lasso catheter is one of a number of different types of catheters made by Biosense. The loop or "lasso" portion that detached in Kapps's heart is basically a single length of nitinol wire. The length of wire has two parts, each of which is covered with a different material: (1) a straight portion that fits inside a lumen in the body of a catheter and that is covered with a plastic sheath; and (2) a curved open loop that projects out of the catheter body and that is covered with what is called a "spine cover." (The spine cover exposes small individual conductive areas attached to electrical leads running along the nitinol wire.)

The open loop's circular shape is perpendicular to the straight portion. Thus, an assembled catheter looks like a lasso being twirled overhead by a cowboy: The curved open loop of the length of nitinol wire corresponds to the loop of the cowboy's lasso, and the catheter body

(which contains the straight portion of the length of nitinol wire) corresponds to the rope in the cowboy's hand.

Roughly speaking, the tip of the Lasso catheter is assembled in two steps. In the first step, the lasso portion — which, as noted, begins as a single length of nitinol wire — is assembled separately from the catheter body. During this step, the spine cover and leads are attached to the open loop of nitinol wire, and the plastic sheath is glued to the straight portion of the wire. (A small area of wire remains exposed between the straight and curved portions of wire.) In the second step, the lasso portion is attached to the catheter body. During this step, polyurethane glue is applied to the (now mostly sheathed) straight portion of the lasso up to the base of the spine cover, and the straight portion is inserted within a lumen of the catheter body. The polyurethane glue forms a dome at the point where the loop exits the catheter body. Thus, the lasso portion is attached to the catheter body by the polyurethane dome and by the polyurethane glue that was applied along the straight portion of the lasso.

During Kapps's procedure, the entire lasso portion — including both the straight part and its sheath, and the loop and its spine cover — pulled cleanly out of the catheter body, leaving the polyurethane dome basically intact. The lasso portion was discarded sometime after Kapps's procedure and thus was not examined by any of the parties' experts. Instead, the experts examined only the catheter body and the polyurethane dome.

As noted, the catheter at issue in this case was made by Biosense. In the Instructions for Use ("IFU") document that accompanies each Lasso catheter, Biosense warns that the catheter is "[f]or one single use only." McLain Aff. [Docket No. 93] Ex. 18 at BW001109; *id.* at BW001110 ("The Biosense Webster LASSO Circular Mapping Catheter is intended for single

patient use only."). Biosense affixes a lot number to each Lasso catheter so that, if a problem arises with respect to a catheter, the circumstances surrounding the making of that catheter can be ascertained.

The catheter at issue in this case was sold by Biosense to the Mayo Clinic and used in a patient. Contrary to Biosense's instruction that the catheter should be used only once, the Mayo Clinic then shipped the used catheter to Ascent for reprocessing, so that the catheter could be used in a second patient. In general, when reprocessing a Lasso catheter, Ascent inspects the catheter, cleans and sterilizes it, and repackages it.

Ascent also takes some steps that go beyond simply inspecting and cleaning the used catheter. In this case, for example, Ascent eliminated the Biosense lot number and replaced it with an Ascent serial number. Barton-Varty Dep. at 121-23.[4] Ascent also provided its own IFU — replacing Biosense's IFU — when it returned the reprocessed catheter to the Mayo Clinic. *See* McLain Aff. [Docket No. 93] Ex. 24. And finally, Ascent provided its own warranty — a warranty that guaranteed not just that the catheter had been properly cleaned, but that the catheter would work properly.

Specifically, the "warranty" section of Ascent's IFU said that the "Medical Facility" (here, the Mayo Clinic) "acknowledges that [Ascent] performs a service, and that Medical

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[4]Various fragments of the transcript of the November 4, 2009 deposition of Moira Barton-Varty, an Ascent executive, are found in the record in at least seven different places. McLain Aff. [Docket No. 38] Ex. 14; McLain Aff. [Docket No. 52] Ex. 28; Lenahan Aff. [Docket No. 78] Ex. D; Jenson Prouty Aff. [Docket No. 90] Ex. D; McLain Aff. [Docket No. 93] Ex. 25; Lenahan Aff. [Docket No. 96] Ex. G; McLain Aff. [Docket No. 105] Ex. 53.

Such haphazard filing of deposition testimony wastes the Court's time and the parties' money. The Court encourages the parties, in the future, to jointly file a single, complete copy of each important deposition.

Facility retains the title and ownership of all medical instruments under this Agreement." *Id.* at AHS002619. The warranty section then provided:

> [Ascent] warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been damaged or opened. [Ascent] warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. [Ascent] shall refund the cost of reprocessing any medical instrument that does not meet the total satisfaction of Medical Facility. . . .
>
> [Ascent] shall indemnify and hold harmless Medical Facility against all claims, demands and liability all sums for which Medical Facility shall become legally obligated to pay as damages caused by bodily injury to patients as a result of [Ascent's] performance of services under this Agreement. . . .

Id.

Further, in a marketing document directed at hospitals and physicians and dated January 2009, Ascent made the following assertions:

> Reprocessed and remanufactured devices from Ascent are cleared for remanufacturing/reprocessing by FDA. This means that in terms of safety and quality, Ascent reprocessed and remanufactured devices are substantially equivalent to OEM [i.e., original equipment manufacturer] devices. Additionally, Ascent devices go through a careful inspection process in which every single device is tested for functionality and visually inspected to ensure process performance. . . .
>
> [W]e do not operate under license from the OEM. In fact, *legally and practically, we are the manufacturers of our reprocessed and remanufactured devices.* We engineer the devices, we remanufacture/reprocess the devices, and we warranty the devices. FDA inspection routines are as stringent, if not more stringent, than those of other manufacturers and assure that our process as well as the devices we market are equivalent to OEM devices. . . .
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> [T]here is no need to ask patients whether they are willing to have a reprocessed or remanufactured device used for their procedure. Ascent devices are substantially equivalent to OEM devices, they

> are warranted by Ascent, and their performance is similar to that of OEM devices. . . .
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> We have never had a patient or a hospital make a claim against us. Should a problem occur, Ascent warranties the devices we remanufacture and reprocess. We carry $25 million in liability coverage. Our customers and clients are fully indemnified against any potential for liability. . . .
>
> [Ascent's] inspection and testing process, which far exceeds that of OEMs in rigor, actually renders Ascent devices more reliable in terms of safety and quality than OEM devices. . . .

Ascent Healthcare Solutions, Questions & Answers: Ascent Answers Hospital Physicians' Remanufacturing/Reprocessing Questions, January 2009 at 1-5, Barton-Varty Jan. 12, 2010 Dep. Ex. 44 at AHS012967-71 (emphasis added).[5]

B. FDA Approval

According to Kapps's theory of this case, FDA approval of Ascent's reprocessing operations is of central importance. The Court does not agree with Kapps, for reasons given below in connection with the Court's discussion of Barkalow's testimony about the FDA. Nonetheless, to provide context, the Court summarizes in general terms the FDA approval process as it relates to the Lasso catheter at issue in this case.

Medical devices are regulated by the FDA under the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. The FDA classifies devices into three categories: Class I, which includes things like elastic bandages and gloves; Class II, which includes things like powered wheelchairs,

[5]This deposition exhibit is found in the record as Exhibit F to one of the Lenahan affidavits. Lenahan Aff. [Docket No. 78] Ex. F.

electrocardiograph machines, and diagnostic catheters; and Class III, which includes things like heart valves, pacemakers, and implantable cerebellar stimulators.[6]

Class I devices are the least regulated; they are subject to only "general controls" such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II devices are somewhat more regulated; they are subject both to general controls and to "special controls" such as performance standards and postmarket-surveillance measures. 21 U.S.C. § 360c(a)(1)(B). Class III devices are the most regulated; with certain exceptions, they are "subject . . . to premarket approval to provide reasonable assurance of [their] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).

Roughly speaking, devices in Class II and Class III (and some in Class I) may not be marketed until they pass through one of two processes: the premarket-*notification* or "510(k)" process, or the more-rigorous premarket-*approval* or "PMA" process.[7] The 510(k) process

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[6] *See generally Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-20 (2008) (discussing FDA regulation of medical devices); FDA, Device Advice: Comprehensive Regulatory Assistance, Overview of Medical Device Regulation — Device Classification, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (last visited Sept. 20, 2011); 21 C.F.R. §§ 880.5075 (elastic bandage), 880.6250 (examination gloves), 890.3860 (powered wheelchair), 870.2340 (electrocardiograph), 870.1200 (diagnostic intravascular catheter), 870.1220 (electrode recording catheter or electrode recording probe), 870.3925 (replacement heart valve), 870.3610 (implantable pacemaker pulse generator), 882.5820 (implanted cerebellar stimulator).

[7] "Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval." FDA, Device Advice: Comprehensive Regulatory Assistance, Overview of Medical Device Regulation — Overview of Device Regulation, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm (last visited Sept. 20, 2011); *see also* FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm (last visited Sept. 20, 2011) ("Unless exempt, FDA will classify your device. Classification identifies the level of regulatory control that is necessary to assure the safety and effectiveness of a medical device. Most importantly, the classification of the device will identify, (continued...)

comes in three versions: traditional, abbreviated, and special.[8] An abbreviated 510(k) application may be used for certain devices that are subject to existing FDA guidance or controls or other recognized standards.[9] A special 510(k) application can be used for a modification to a device that has previously been cleared under the 510(k) process.[10]

Most Class II devices go through some version of the 510(k) process. Class III devices developed after the MDA's effective date must go through the much more rigorous PMA process, which involves a lengthy application and extensive FDA review. *See Riegel*, 552 U.S.

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[7](...continued)
unless exempt, the marketing process (either premarket notification [510(k)] or premarket approval (PMA)) the manufacturer must complete in order to obtain FDA clearance/approval for marketing." (bracketed material in original)).

[8]FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device — 510(k) Submission Methods, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm (last visited Sept. 20, 2011).

[9]FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device — How to Prepare an Abbreviated 510(k), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134574.htm (last visited Sept. 20, 2011) ("The Abbreviated 510(k) relies on the use of guidance documents, special controls, and recognized standards. . . . In an Abbreviated 510(k) submission, manufacturers elect to provide summary reports on the use of guidance documents and/or special controls, or declarations of conformity to recognized standards, to expedite the review of a submission.").

[10]FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device — 510(k) Submission Methods, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm (last visited Sept. 20, 2011) ("The Special 510(k) is used for device modifications and utilizes the design controls aspect of the Quality System (QS) regulation (21 CFR 820.30). Special 510(k)s may be submitted for a modification to a device that has been cleared under the 510(k) process. If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process can serve as the basis for clearing the application.").

at 317-18. But certain Class III devices that were developed before the MDA's effective date may be marketed after passing through only the 510(k) process. *See id.*

The Lasso catheter at issue in this case is a Class II device, and it was subject to two different approval processes — one that applied to Biosense (when the catheter was made) and one that applied to Ascent (when the catheter was reprocessed).

Biosense obtained 510(k) approval of the Lasso catheter in August 2000 through a special 510(k) application. Sheridan Rept. at 14.[11]

Ascent filed a 510(k) application in August 2001 seeking approval to market various reprocessed devices. Among the devices listed in Ascent's 510(k) application were 68 different mapping catheters made by Biosense. *Id.* The FDA approved the 510(k) application in August 2002, and then again in 2004, after Ascent submitted additional information required under FDA regulations imposed on medical-device reprocessors in 2003. *Id.* at 13-14.

The specific model of Lasso catheter at issue in this case was not among the 68 Biosense mapping catheters listed in Ascent's 510(k) application that was approved in August 2002 (and again in 2004). Instead, in December 2002, Ascent made an internal decision that the Lasso was sufficiently similar to some of the 68 models that had been listed in Ascent's earlier 510(k) application that Ascent was not required to file a separate 510(k) application with respect to the Lasso. In the language of the medical-device industry, Ascent decided that the Lasso was a "line extension" of a previously approved device, rather than a new device. A line extension does not require its own 510(k) application. *Id.* at 16-17.

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[11]The expert report of Robert L. Sheridan, a former FDA employee and an expert witness for Ascent, is found in the record as Exhibit 14 to one of the McLain affidavits. McLain Aff. [Docket No. 52] Ex. 14.

Because medical-device manufacturers are continuously developing and improving their products, manufacturers must often decide whether changes to a device are sufficiently insignificant that the changed device is a mere line extension or sufficiently significant that the changed device requires a new 510(k) application. Under 21 C.F.R. § 807.81, a new 510(k) application is required when a manufacturer makes "[a] change or modification in [a previously approved] device that could significantly affect the safety or effectiveness of the device . . . ." 21 C.F.R. § 807.81(a)(3)(i). Because some modifications to a device will not "significantly affect" its safety or effectiveness, the FDA does not expect or require a device manufacturer to submit a new 510(k) application every time a device is modified.[12] Instead, the manufacturer must decide whether to submit a new 510(k) application in light of the FDA's guidance about what modifications are likely to require submission of such an application.[13]

[12] *See* FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device — Is a new 510(k) required for a modification to the device?, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134575.htm (last visited Sept. 20, 2011) ("It is not FDA's intent that a 510(k) must be submitted for every modification.").

[13] *Id.* ("When a 510(k) holder decides to modify an existing device, the holder must decide whether the proposed device modification(s) requires submission of a 510(k). . . . FDA believes that the 510(k) holder is best qualified to determine when modifications to their device could significantly affect safety or effectiveness."); Office of Device Evaluation, FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device* (Jan. 10, 1997), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm (last visited Sept. 20, 2011).

C. Expert Opinions

1. Bruce H. Barkalow, Ph.D.[14]

Barkalow received a Ph.D. in biomedical engineering in 1972. Since then, he has been a biomedical-engineering consultant to hospitals, medical-device companies, and the FDA. He has served as the president of a medical-device manufacturer since 2005. He has been an adjunct professor of biomedical engineering at Michigan Technological University since 1992, and he has regularly given presentations and published articles in the field of biomedical engineering.

In preparing his expert report, Barkalow reviewed medical records relating to Kapps, engineering documents and product information from both Biosense and Ascent, and deposition testimony from various witnesses. Barkalow physically inspected the catheter at issue, and he observed the testing and inspection of the catheter conducted by Ascent's expert in March 2010.

Barkalow's opinions in his expert report differ somewhat from the opinions he later expressed in his deposition. The Court therefore first summarizes Barkalow's expert report, then turns to his deposition testimony.

a. Barkalow's Expert Report

Based on the March 2010 testing and inspection of the catheter that came apart in Kapps's heart, Barkalow found that the used catheter differed from an unused comparison catheter in several ways. First, the polyurethane dome of the used catheter was darkened, not

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[14]The opening and rebuttal expert reports of Bruce H. Barkalow, Ph.D. are found in the record as Exhibits 11 and 18, respectively, to one of the McLain affidavits. McLain Aff. [Docket No. 52] Exs. 11, 18.

Various fragments of the transcript of Barkalow's October 7, 2010 deposition are found in the record at at least three different places. Arthur Aff. [Docket No. 62] Ex. 2; Lenahan Aff. [Docket No. 78] Ex. K; Lenahan Aff. [Docket No. 112] Ex. B.

clear. Second, the used catheter had what appeared to be a smear of polyurethane on the outside of the body of the catheter, while the unused catheter had no such smear. Third, the lasso portion was missing from the used catheter, and it appeared to have pulled cleanly out of the catheter without damaging the surrounding polyurethane adhesive or the lumen of the catheter. Barkalow Rept. at 8-9.

Based on his review of the evidence, Barkalow concluded that the lasso portion of the used catheter pulled out because of "inadequate adhesion" between the lasso portion and the catheter body. *Id.* at 10. Barkalow also opined that despite becoming entangled in Kapps's mitral valve, "the [lasso] portion should not have come separated from the main catheter body." *Id.* In other words, according to Barkalow the lasso portion of a nondefective catheter would have been glued strongly enough to the catheter body to withstand the forces exerted during Kapps's procedure without pulling out of the catheter body.

Barkalow did not, however, offer a clear opinion that Biosense made a defective catheter. Indeed, Barkalow said that the catheter "was manufactured with sufficient structural integrity to perform the initial use." *Id.* at 10. As noted above, Biosense had warned that its catheter was "[f]or one single use only," and thus the "initial use" referred to by Barkalow was the *only* use that was consistent with Biosense's instructions. Far from blaming Biosense for making a defective catheter, then, Barkalow opined that "[t]he subject catheter on its second use *after remanufacture by Ascent* was defective and unreasonably dangerous . . . ." *Id.* (emphasis added).

To support his opinion that the catheter was defective after Ascent's reprocessing, Barkalow relied on the fact that the lasso portion of the catheter had pulled cleanly out of the catheter body under what Barkalow considered to be predictable circumstances: entrapment in

Kapps's mitral valve followed by ordinary attempts at extrication. Barkalow cited only one other piece of evidence to show that the catheter was defective: the smear of polyurethane glue on the catheter body's exterior.

According to Barkalow, the smear showed that the catheter had "either an original manufacturing fault or a reprocessing fault such as the inappropriate use of a chemical that affected the clear [polyurethane] dome material and caused it to disperse onto the main catheter body." *Id.* In his rebuttal expert report, Barkalow suggested that the polyurethane smear was more likely to have been made during manufacturing than reprocessing. He said: "It is not obvious that this anomalous spread of material that appears to be [polyurethane] could have happened in the reprocessing steps. It may be an indication of a manufacturing problem." Barkalow Rebuttal Rept. at 2-3.

Barkalow did not otherwise connect the polyurethane smear to the device's failure. In fact, Barkalow said that the "failure of the adhesion bond" between the lasso and the catheter body "could be a result" of four different things, two being the fault of Biosense and two being the fault of Ascent. Barkalow Rept. at 10.

With respect to Biosense, Barkalow said that the catheter might have had an unspecified "latent problem" caused by "Biosense manufacturing technique/materials," and that because of this latent problem, the catheter — from the time it was first made — was too weak to withstand "normal mitral valve extrication technique . . . ." *Id.* On this theory, the catheter would have failed in the *first* patient if it had become entrapped in that patient's mitral valve, and the catheter survived the procedure only because it did not become entrapped.

Alternatively, Barkalow said that the catheter might have failed because it "could not withstand the Ascent remanufacture processes" and thus "could not withstand normal mitral valve extrication techniques . . . ." *Id.* On this second theory, the catheter could have survived entrapment and normal extrication efforts in the first patient, and the catheter failed during Kapps's procedure only because it was weakened by reprocessing. Implicit in this second theory — if it is to be a basis for finding Biosense liable — are two assumptions: (1) that the catheter, if properly made, should have been able to withstand entrapment and extrication after being subjected to ordinary reprocessing techniques; and (2) that the catheter was in fact subjected only to ordinary reprocessing techniques.

With respect to Ascent, Barkalow said that its reprocessing might have damaged the catheter in one or both of two ways. First, Ascent might have damaged the catheter by "us[ing] inappropriate chemicals" that "chemically weakened" the catheter. *Id.* Second, Ascent might have "physically damaged" the catheter during reprocessing. *Id.* at 11.

Of course, these four theories are not mutually exclusive. For instance, the catheter might have been so defective when it left Biosense's hands that it could not survive ordinary entanglement in and extrication from a mitral valve — and the catheter might *also* have been subjected to such abuse by Ascent that, even if it had not been defectively made by Biosense, the catheter would have failed just as it did.

Barkalow opined in his report, however, that "it is most likely that the subject Biosense LASSO catheter was damaged by the nonvalidated Ascent remanufacturing process such that [it] could not withstand normal mitral valve extrication techniques as used by Dr. Packer." *Id.* In

offering this opinion, Barkalow did not distinguish between chemical and physical damage by Ascent, and he did not appear to suggest that the catheter was defectively made by Biosense.

Finally, Barkalow opined that Ascent violated FDA regulations by not securing 510(k) approval for reprocessing Lasso catheters. This particular opinion underlies Barkalow's description of Ascent's reprocessing techniques as "nonvalidated" (or "unvalidated"). *Id.*

b. Barkalow's Deposition Testimony

As noted, Barkalow's deposition testimony differed in some respects from his expert report. At his deposition, Barkalow said that the smear of polyurethane on the outside of the catheter must have occurred during the catheter's manufacture, not during reprocessing. Barkalow Dep. at 79 ("[T]he only source of the polyurethane is from Biosense, it's not from Ascent. And the isopropyl alcohol I don't think is a strong enough solvent to have caused the polyurethane to smear over the body."). But he gave equivocal and conflicting testimony about whether the smear indicated that a flaw that existed when the catheter left Biosense's hands — that is, before it was reprocessed by Ascent — contributed to its failure during the procedure on Kapps.

On the one hand, when Barkalow was asked whether the catheter was defective before it was reprocessed, he said several times that he *did not know*. For instance, Barkalow and a defendant's attorney had this exchange:

> Q: [D]o you have an opinion in this case as to whether the electrophysiology catheter was defective and unreasonably dangerous prior to reprocessing?
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> A: It obviously survived the first utilization, so it was safe for that, a single use. That's all I can really say. But for the second application, it's a different story.

> Q: So you don't have an opinion?
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> A: I don't know if that device, had it been entangled — let's say that you could go back in time and you could recreate the exact incident that Dr. Packer encountered, but the Biosense Webster catheter was on its first deployment. Would it have separated? I think that's what you're asking. *We don't know.* But all I can say is there's something not right with the polyurethane on that particular catheter.

Id. at 75-76 (emphasis added); *see also id.* at 75 ("[W]hether or not it would be strong enough to withstand the mitral valve entanglement in the first use, I don't know."); *id.* ("Q: Do we know whether [the catheter] had that integrity before reprocessing or not? A: We don't know."); *id.* at 33 ("Q: Did that bond deficiency exist before the reprocessing or was it caused by the reprocessing? A: I don't really know. . . .").

Yet immediately after saying that he did not know whether the catheter was defective when it left Biosense's hands, Barkalow opined that there was a "good possibility" that the polyurethane holding the lasso to the catheter body was weaker than it should have been even before the catheter was reprocessed by Ascent. Barkalow and a defendant's attorney had this exchange:

> Q: Do you know what the exact mechanisms of separation were after reprocessing?
>
> A: Yes. The polyurethane adhesion bond was weak, and the LASSO portion pulled out of the catheter body.
>
> Q: And when was that weakness introduced into the catheter?
>
> A: I would say that there's a good possibility that it was introduced in the manufacturing of it because it didn't follow all of the techniques, as evidenced by the polyurethane being on the catheter body . . . .

Id. at 77-78. In this testimony, Barkalow seemed to assert that the smear of polyurethane glue on the outside of the catheter shows that the catheter was defectively weak, contrary to his testimony that he did not know whether the catheter was defectively weak before its first use.

When asked to explain how the polyurethane smear related to the hypothesized weakness of the glue joint between the lasso and the catheter body, Barkalow could not do so. For one thing, he did not offer a specific opinion about how the smear arose. Instead, he speculated as to three possible causes: The polyurethane itself might have been so runny "that it ran out over the body of the catheter . . . ." *Id.* at 144. Or an assembler, through "extra handling," might have "smeared the polyurethane" on the catheter. *Id.* Or there may have been "excess" polyurethane at some step that "smear[ed] out" during assembly. *Id.* at 149.

More important, whatever the source of the smear may have been, Barkalow did not explain how the smear was evidence of the catheter's weakness. After Barkalow described the smear as "indicative of some sort of manufacturing anomaly," Barkalow and a defense attorney had this exchange:

> Q: . . . The manufacturing anomaly that you described, the smearing of the [polyurethane] on the outside of the catheter body, would that alone affect the structural integrity or the strength of the catheter?
>
> A: Not necessarily. It may. I mean if you just talk about everything else is followed perfectly and then you add smearing of the polyurethane on top of it, no.
>
> Q: So just by virtue of the fact that it has been assembled, there's a dome, and there's some smear of polyurethane wouldn't necessarily indicate that there's a defect in the catheter, correct?

A: It means something wasn't right in the manufacturing process, but that wasn't the extent of it. We don't know exactly.

Q: But it doesn't necessarily follow that there is a structural defect that would affect the strength of the catheter, correct?

A: That's right, but it's consistent with what happened in this case. It's suspect.

Q: Well, how is it suspect?

A: It's suspect because after the reprocessing, the catheter came apart.

Q: Right. So before the reprocessing would it be suspect?

A: We don't necessarily know because we don't believe that it was trapped in the first patient's mitral valve.

. . .

Q: [W]hat you're saying though is . . . there's nothing about the smearing of the catheter on the outside . . . that would necessarily by itself affect the strength and function of the catheter, correct?

A: In isolation, that's correct.

Id. at 159-61.

As this exchange indicates, Barkalow's opinion that Biosense made a defective catheter — to the extent that he even offers this opinion — depends largely on the fact that the catheter failed during Kapps's procedure. Indeed, the catheter's failure was the sole basis for Barkalow's speculation that too little polyurethane may have been used during assembly. *Id.* at 158 (testifying that it is "a possibility" that too little polyurethane was used, but responding "that's correct" to an attorney's assertion that "other than the sheer fact of separation, you have no other indicia that there was too little polyurethane applied"). Notably, Barkalow's speculation about

too *little* polyurethane causing the catheter's failure is inconsistent with his speculation that the smear on the catheter body resulted from the application during assembly of too *much* polyurethane. *Compare id.* at 149 ("if there's excess [polyurethane], it could smear out") with *id.* at 154-55 ("there could have been an insufficient amount of polyurethane applied on the inside").

With respect to Ascent, Barkalow likewise testified that the catheter's failure showed that it was defective. He summarized his opinion as follows:

> I think if you look at the overall situation here, it's fairly straightforward. What happened was that Ascent assumed responsibility for the used catheter, put it through its nonvalidated reprocessing technique, and then it broke. And there's no evidence here that Dr. Packer used [undue] force, so that means something's wrong with the catheter.

Id. at 118.

Barkalow identified a number of procedures connected to Ascent's reprocessing that might have weakened the catheter. Specifically, he said that the catheter might have been damaged during any or all of eight steps: (1) collecting the used catheter by hospital personnel after its first use and before reprocessing; (2) shipping the catheter to Ascent for reprocessing; (3) untangling the catheter from other catheters at Ascent; (4) exposing the catheter to isopropyl alcohol either by wiping the catheter with alcohol or by soaking the catheter in a disinfecting solution called Cavicide that contains isopropyl alcohol; (5) cleaning the catheter with a nylon brush; (6) manually inspecting the catheter by running fingers along it; (7) manipulating the catheter during other inspection procedures; and (8) shipping the reprocessed catheter to a hospital for use. *Id.* at 88-91. Barkalow did not say that any one of these steps, alone, damaged the catheter. Rather, he said:

> I think it's a combinatorial sort of thing; that it's most probable that all of these steps that we've talked about moved the situation in the wrong direction to weaken the polyurethane joint that was critical.

Id. at 88.

Barkalow did, however, discuss in some detail Ascent's use of isopropyl alcohol during reprocessing as a potential cause of the catheter's failure. Barkalow was unable to say exactly what happens when polyurethane adhesive comes into contact with isopropyl alcohol. *Id.* at 80. In fact, he admitted that he was not "a recognized expert in analyzing and opining upon how polyurethane adhesive reacts to other chemicals[.]" *Id.* at 28. In concluding that Ascent's use of solutions containing isopropyl alcohol might have damaged the catheter's glue joint, Barkalow relied primarily on the fact that Biosense recommends against exposing the catheter to isopropyl alcohol, as this exchange between him and a defendant's attorney shows:

> Q: What happens when you introduce polyurethane adhesive to isopropyl alcohol?
>
> A: I haven't had enough time to really investigate that. I think that's something that we need to look at a bit further.
>
> Q: As you sit here, do you know?
>
> A: I don't know of the exact mechanisms, but I know that it's contraindicated by Biosense.
>
> Q: Why is it contraindicated?
>
> A: Obviously because it could damage the catheter. They wouldn't contraindicate it if that wasn't the case. There's really no other reason.
>
> . . .
>
> Q: Are you qualified to talk about the chemical reaction between isopropyl alcohol and polyurethane adhesive?

> A: Sure. I can say that isopropyl alcohol is a solvent and it interacts with plastics and it's not appropriate for all of them to be exposed to it without some kind of damage, and Biosense has clearly stated that . . . isopropyl [alcohol] is contraindicated to be used with this catheter.

Id. at 80-82.

Barkalow also testified that Ascent did not properly inspect the catheter before reprocessing it. According to Barkalow, an inspector would have spotted the polyurethane smear on the outside of the catheter, and the catheter "would have been culled and not reprocessed." *Id.* at 16.

The significance of Ascent's alleged failure to inspect is unclear. At one point, Barkalow asserts that the catheter "should never have been reprocessed in the first place" because "there may have been something wrong with this catheter because the polyurethane is not supposed to be on the body . . . ." *Id.* at 32; *see also id.* at 59 ("I don't think Ascent should have reprocessed this catheter."). But when Barkalow was asked a few moments later whether a defect in the catheter's glue joint existed before reprocessing or was caused by reprocessing, Barkalow replied, "*I don't really know.* I can say that this particular Biosense catheter has an anomalous appearance." *Id.* at 33 (emphasis added).

Barkalow also testified — consistent with his expert report — that Ascent violated FDA regulations when it failed to secure 510(k) approval that was specific to the Lasso, but instead used the "line extension" method. *Id.* at 17, 45-52.

2. David G. Benditt, M.D.[15]

Dr. David G. Benditt is a specialist in cardiovascular medicine and cardiac electrophysiology. He is a professor at the University of Minnesota Medical School and a co-director of the school's Cardiac Arrhythmia Center. Benditt Rept. at 1. His qualifications as a medical expert are undisputed.

In his expert report, Benditt offered opinions on three subjects: (1) the adequacy of the warnings provided by Biosense and Ascent with respect to the Lasso catheter; (2) the differences between the Lasso catheter and the catheters that were listed in Ascent's 510(k) application; and (3) the cause of Kapps's injuries.

With respect to the warnings, Benditt said:

> I am prepared to testify that it was inappropriate for [Biosense and Ascent] not to warn physicians or patients about a known, potentially dangerous defect in the Biosense Webster Circular Mapping Catheter ("Lasso catheter") that allowed the Lasso catheter to become entrapped in the mitral valve. Additionally, I will testify that it was inappropriate for [Biosense and Ascent] not to warn physicians about how to properly untangle the Lasso catheter after it became entrapped in the mitral valve. This failure to communicate played a substantial part in causing Dr. Kapps'[s] injuries.

Benditt Rept. at 4. According to Benditt, "doctors are not generally aware of the heightened risk" of mitral-valve entrapment when using the Lasso catheter, and thus, "[d]octors should be warned that careful manipulation of the LASSO Catheter is mandatory and particularly important." *Id.*

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[15]The expert report of David G. Benditt, M.D. is found in the record as Exhibit 6 to one of the McLain affidavits. McLain Aff. [Docket No. 52] Ex. 6.

The complete transcript of Benditt's October 23, 2010 deposition is in the record as McLain Aff. [Docket No. 99] Ex. 26. Fragments of the transcript are found in at least two other places. McLain Aff. [Docket No. 52] Ex. 39; Jenson Prouty Aff. [Docket No. 90] Ex. A.

at 10. Benditt also said that Biosense and Ascent "should have provided instructions for catheter removal after entanglement," but he did not describe what those instructions should have been. *See id.* at 10-11.

With respect to Ascent's 510(k) application, Benditt said that the Lasso was "substantially different in design, construction and application" from the Halo model of catheter that Ascent expressly listed in its 510(k) application. *Id.* at 12. Based on this assessment, Benditt further opined that "[i]t was inappropriate for Ascent to have used the HALO as a predicate device" for the Lasso when Ascent was deciding whether to file a new 510(k) application for the Lasso. *Id.*

Given Benditt's experience and training as a cardiac electrophysiologist, he is qualified to opine about the differences betwee the Halo and Lasso catheters. But Benditt is not an expert with respect to FDA regulations. Accordingly, the Court ruled after the March 17, 2011 hearing that Benditt could not offer an opinion about whether Ascent properly treated the Lasso as a line extension of the Halo when deciding whether to file a 510(k) application with respect to the Lasso. Order Mar. 18, 2011 at 5-6.

Finally, Benditt opined that "Dr. Kapps'[s] injuries were directly caused by the failure of the LASSO catheter . . . ." *Id.* at 4. Relatedly, Benditt said that he expected the Lasso catheter "to be strong enough to withstand" the force applied by Packer when he tried to extricate the Lasso's loop portion from Kapps's mitral valve. *Id.* at 11.

II. DISCUSSION

A. Legal Principles

1. Summary Judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute over a fact is "material" only if its resolution might affect the outcome of the lawsuit under the substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute over a fact is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

2. Admissibility of Expert Testimony

Rule 702 of the Federal Rules of Evidence provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Put simply, expert testimony is admissible under Rule 702 only if it is both reliable and relevant. *Daubert*, 509 U.S. at 589; *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 448 (8th Cir. 2010).

The proponent of expert testimony bears the burden of establishing the reliability and relevance of the proposed testimony. *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006). Expert testimony is reliable only if the expert is qualified to render the opinion and the

underlying methodology is scientifically valid. *See Daubert*, 509 U.S. at 589-90; *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010). Expert testimony is relevant only if the expert properly applies her methodology or reasoning to the facts in issue. *See Daubert,* 509 U.S. at 591-93; *Barrett*, 606 F.3d at 980.

District courts have wide latitude in determining whether an expert's testimony is reliable. *Olson v. Ford Motor Co.*, 481 F.3d 619, 626 (8th Cir. 2007). In assessing reliability, district courts consider such factors as: (1) whether the theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; (4) whether the theory or technique is generally accepted in the scientific community; (5) whether the expertise was developed for litigation or naturally flowed from the expert's research; and (6) whether the proposed expert ruled out other alternative explanations. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686-87 (8th Cir. 2001); *see also Daubert*, 509 U.S. at 592-94. Because the reliability inquiry is necessarily fact-specific, no single standard for reliability exists. *See Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005). Instead, these factors are flexible and should be considered as the case demands. *Id.*

In general, courts should resolve doubts about the usefulness of an expert's testimony in favor of admissibility. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006). But overly speculative testimony should not be admitted. *Junk,* 628 F.3d at 448; *Grp. Health Plan, Inc. v. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) ("A certain amount of speculation [by an expert] is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission."). For example, a court should not

admit opinion evidence that "is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Thus, when "there is simply too great an analytical gap between the data and the opinion proffered," an expert's opinion should be excluded. *Id.*; *Junk,* 628 F.3d at 448 (quoting *Joiner*).

3. Products Liability Under Minnesota Law

Under Minnesota law, a plaintiff can recover in a products-liability action by showing three things: (1) the product at issue was "in a defective condition, unreasonably dangerous for its intended use"; (2) the product's defect existed when the product left the defendant's control; and (3) the defect was the proximate cause of the plaintiff's injury. *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (Minn. 1971); *see also Schafer v. JLC Food Sys., Inc.*, 695 N.W.2d 570, 576 (Minn. 2005) (citing *Lee*). This is the doctrine of strict liability as set forth in Restatement (Second) of Torts § 402A, which Minnesota has adopted. *Lee*, 188 N.W.2d at 432; *McCormack ex rel. McCormack v. Hankscraft Co.*,154 N.W.2d 488, 499-501 (Minn. 1967).

In a products-liability case, the distinction between theories of strict liability and negligence is typically insignificant. As *Lee* explained, under the theory of strict liability, "[w]hile in conventional tort terms no proof of negligence is necessary, in many cases proof of a defect may simply be a substitute word for negligence." 188 N.W.2d at 432. Indeed, the Minnesota Supreme Court held in *Bilotta v. Kelley Co.* that with respect to failure-to-warn and design-defect claims, the theories of negligence and strict liability are effectively merged into a single theory of products liability. 346 N.W.2d 616, 623 (Minn. 1984) ("[A]ssuming proper instruction to ensure the broadest theory of recovery, a trial court could properly submit a design-defect or failure-to-warn case to a jury on a single theory of products liability.").

Bilotta leaves open the theoretical possibility of a distinction between theories of negligence and strict liability in a manufacturing-defect case. *Id.* at 622 ("It has been suggested by commentators that . . . strict liability and negligence are distinct theories in manufacturing flaw cases . . . ."); *Johnson v. Zimmer, Inc.*, No. 02-1328, 2004 U.S. Dist. LEXIS 6007, at *32, 2004 WL 742038, at *10 (D. Minn. Mar. 31, 2004) (citing *Bilotta* for the proposition that "[n]egligence and strict liability are distinct theories in manufacturing flaw cases"). But the core of a manufacturing-defect case is some manufacturing flaw — some deviation from a flawless product — that renders a product unreasonably dangerous. *Bilotta*, 346 N.W.2d at 622. If a dangerous manufacturing flaw existed and resulted from negligence, a plaintiff could in theory recover in negligence; if a dangerous flaw existed but did *not* result from negligence, a plaintiff could recover in strict liability. Either way, the plaintiff would be able to recover for injuries caused by a product rendered unreasonably dangerous by a manufacturing flaw. *See Lee*, 188 N.W.2d at 432.

Further, in a manufacturing-flaw case, a defendant may rely on the doctrine of res ipsa loquitur to establish, through circumstantial evidence, that a product was dangerously defective, and the plaintiff may recover in either negligence or strict liability. As the Minnesota Supreme Court held in *Holkestad v. Coca-Cola Bottling Co. of Minnesota*:

> When a plaintiff has proved that he was injured by a product claimed to have been defective, and where the claimed defect is such that there is circumstantial evidence from which it can be inferred that it is more probable than not that the product was defective when it left defendant's hands, absent plaintiff's own want of care or misuse of the product, there is an evidentiary basis for submitting the issue of liability to the jury on both the theory of negligence and strict liability in tort.

180 N.W.2d 860, 865-66 (Minn. 1970). In a manufacturing-flaw case based on a theory of res ipsa loquitur, the doctrines of negligence and strict liability are connected because "the factor essential to the application of res ipsa loquitur — that it must be the kind of event which does not occur in the absence of negligence — is a circumstance tending to prove a [manufacturing] defect . . . ." *Id.* at 866.

The Minnesota Supreme Court's application in *Holkestad* of res ipsa loquitur to products-liability cases is consistent with Restatement (Third) of Torts: Products Liability § 3, which provides:

> It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff:
>
> > (a) was of a kind that ordinarily occurs as a result of product defect; and
> >
> > (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.

Restatement (Third) of Torts: Products Liability § 3 (1998).

This consistency between *Holkestad* and Restatement (Third) § 3 was expressly noted by the Minnesota Supreme Court in *Schafer v. JLC Food Systems, Inc.*, 695 N.W.2d 570, 576 & n.2 (Minn. 2005). *Schafer* held:

> [I]n defective food products cases a plaintiff may reach the jury, without direct proof of the specific injury-causing object or substance, when the plaintiff establishes by reasonable inference from circumstantial evidence that: (1) the injury-causing event was of a kind that would ordinarily only occur as a result of a defective condition in the food product; (2) the defendant was responsible for a condition that was the cause of the injury; and (3) the

> injury-causing event was not caused by anything other than a food product defect existing at the time of the food product's sale.

Id. at 577. In effect, *Schafer* was an application to a defective-food-products case of res ipsa loquitur, which Minnesota has long held to apply in ordinary products-liability cases. *See id.* at 576 ("Permitting the use of circumstantial evidence in [defective-food-products] cases is consistent with our jurisprudence on the use of circumstantial evidence to infer negligence in other contexts.").

B. Admissibility of Barkalow's Expert Testimony

Although defendants point out that Barkalow is not a medical doctor and is not an expert in the properties of polyurethane adhesives, they do not seriously challenge his basic qualifications as an expert in medical devices. And to the extent that defendants do argue that Barkalow is not qualified as an expert, the Court rejects the argument. Barkalow has extensive training and experience in biomedical engineering, and the Court finds that Barkalow's expertise is sufficiently related to the issues in this case to render him qualified to offer expert testimony.

The more difficult question is whether Barkalow's testimony is sufficiently reliable to be admissible. Because Barkalow's testimony differs with respect to Biosense and Ascent, the Court discusses separately the admissibility of his testimony with respect to each defendant.

1. Barkalow's Testimony With Respect to Biosense

Biosense argues that Barkalow's testimony with respect to a manufacturing defect by Biosense is unreliable under *Daubert* and Rule 702 and thus should be excluded. The Court agrees.

To begin with, it is questionable whether Barkalow ever actually opined — either in his expert report or in his deposition testimony — that the catheter was defective when it left

Biosense's hands. Specifically, in his expert report, Barkalow said that "[t]he subject catheter *on its second use after remanufacture by Ascent* was defective and unreasonably dangerous . . . ." Barkalow Rept. at 10 (emphasis added). Notably, Barkalow did not assert that the catheter was "defective and unreasonably dangerous" *before* it was reprocessed. Further, when asked at his deposition whether the catheter was defective before it was reprocessed, Barkalow said — over and over again — that he simply did not know. *See* Barkalow Dep. at 33, 75-76.

But Barkalow did sometimes seem to assert at his deposition — although not in his expert report — that the catheter was defective because of the smear of polyurethane on the exterior of the catheter body. To the extent that Barkalow's testimony can be interpreted as making an assertion that the smear shows that the catheter was defectively made by Biosense, the Court excludes Barkalow's opinion as unreliable.

Under Rule 702 and *Daubert*, an expert witness must reliably connect his opinion to the underlying data. The data at issue here is actually a single datum: a smear of polyurethane glue that was visible on the exterior of the Lasso catheter. Barkalow does not offer any reason for connecting that smear to the catheter's failure. In effect, Barkalow's opinion equates correlation — i.e., a smear existed, and the catheter failed (facts that are not disputed) — with causation — i.e., the catheter failed because of a gluing defect that also gave rise to a smear (a causal connection that Barkalow does not establish). Nothing but Barkalow's say-so (his *ipse dixit*) connects the smear on the outside of the catheter to the catheter's failure, and thus "there is simply too great an analytical gap" between Barkalow's opinion and the underlying facts to permit Barkalow to testify as an expert against Biosense. *See Joiner*, 522 U.S. at 146; *Junk,* 628 F.3d at 448 (quoting *Joiner*).

2. Barkalow's Testimony With Respect to Ascent

Barkalow offered two separate opinions with respect to Ascent. First, he opined that the catheter was damaged by Ascent during reprocessing and was therefore defective. Second, he opined that Ascent violated FDA regulations by using the line-extension procedure to obtain clearance to reprocess Lasso catheters instead of using the more-involved 510(k) approval procedure. The Court addresses in turn Ascent's objections to these two opinions.

a. Barkalow's Opinion About the Catheter's Defect

Ascent breaks down Barkalow's opinion about the catheter's defect into two theories: (1) the theory that alcohol degraded the polyurethane holding the lasso portion inside the catheter body, and (2) the theory that some kind of physical mishandling weakened the joint between the lasso portion and the catheter body. Ascent Mem. Supp. Mot. Exclude Barkalow at 2-3 [Docket No. 61]. Ascent criticizes the second theory (physical mishandling) as being: (1) untested; (2) unpublished and not subject to peer review; (3) not generally accepted; and (4) developed for litigation. *Id.* at 14-17. Ascent criticizes the first theory (glue degradation) on these same four grounds, as well as on a fifth ground: having an unknown error rate. *Id.* at 8-12. Ascent also argues that Barkalow is not sufficiently knowledgeable about polyurethane to offer an opinion about whether Ascent's use of alcohol-containing compounds in reprocessing may have degraded the glue joint. *Id.* at 12-13.

The Court agrees that Ascent has identified a number of genuine weaknesses in Barkalow's testimony. The Court does not, however, agree that Barkalow's opinion with respect to Ascent is so speculative or unreliable that it should be excluded.

Ascent criticizes Barkalow for not singling out a specific step in Ascent's reprocessing procedure as the step in which the catheter was damaged. *Id.* at 14 ("Dr. Barkalow's hypothesis is based solely on speculation that one or more steps undertaken by Ascent during reprocessing *could* have the potential to weaken the catheter."). But under Minnesota's products-liability law, Kapps is not *required* "to prove specifically what defect caused the incident, but may rely upon circumstantial evidence from which it can reasonably be inferred that it is more probable than not that the product was defective when it left [Ascent's] control." *Lee*, 188 N.W.2d at 434. Because Kapps need not prove specifically which aspect of Ascent's process rendered the Lasso defective, Barkalow may testify that the broken catheter was weaker than it should have been and that one or more of several different steps in Ascent's reprocessing procedure may have contributed to the catheter's weakness.

The core of Barkalow's opinion is, as he said in his deposition, "fairly straightforward." Barkalow Dep. at 118. According to Barkalow: (1) Ascent reprocessed the catheter; (2) Packer did not use excessive force when the catheter became entangled in Kapps's mitral valve; (3) the catheter's tip (i.e., the lasso portion) nonetheless pulled out of the catheter body; ergo (4) the catheter was defective. *Id.*

Barkalow's conclusion that the catheter was defective rests on the premise that a *nondefective* catheter would not have failed had it been subjected to the same conditions as the catheter at issue in this suit. And Barkalow offered exactly this opinion in his expert report when he said that despite becoming entangled in Kapps's mitral valve, "the [lasso] portion should not have come separated from the main catheter body." Barkalow Rept. at 10. Given Barkalow's expertise in biomedical engineering, the Court finds that he is qualified to offer this opinion.

Whether a medical device should be expected to withstand certain conditions is a factual question on which expert testimony is generally required. Thus, in *Kaplon v. Howmedica, Inc.*, the Eighth Circuit upheld judgment as a matter of law dismissing a plaintiff's products-liability claim where the plaintiff argued that a surgical nail was defective because it failed seven months after implantation when (according to the plaintiff) it should have lasted twelve months. 83 F.3d 263, 266 (8th Cir. 1996). Two doctors testified in *Kaplon*, and neither of them testified "that the nail should have lasted twelve months or that they believed the nail was defective because it did not." *Id.* at 267. The Eighth Circuit held that the evidence was "not sufficient to support a finding that a [surgical] nail that does not last twelve months is defective" and that "[s]uch a finding would depend upon unwarranted speculation or conjecture on matters outside the scope of the jury's experience." *Id.*

In this case, a jury of laypersons could not, on its own, decide whether the tip of a Lasso catheter should have been able to withstand entrapment in Kapps's mitral valve without separating from the catheter body. Just as a layperson cannot know how long a nondefective surgical nail should last, a layperson cannot know what type of forces a nondefective catheter should be able to withstand without coming apart.

Barkalow offers precisely the type of testimony that was missing in *Kaplon*: testimony that the medical device at issue was defective because it failed under circumstances in which a defect-free device would *not* have failed. Moreover, Benditt also opined that a nondefective Lasso would not have failed as did the Lasso used in treating Kapps.[16] And Packer, testifying as

[16]Benditt Rept. at 11 ("Based on the evidence available, it does not appear that Dr. Packer used an abnormal amount of force when manipulating the LASSO Catheter inside Dr. Kapps. As (continued...)

a fact witness, said essentially the same thing.[17] Barkalow's, Benditt's, and Packer's testimony on this point is directly relevant to a strict-liability claim brought under the theory of res ipsa loquitur. *See Lee*, 188 N.W.2d at 434-35.

b. Barkalow's Opinion About FDA Approval

The Court excludes Barkalow's opinion with respect to FDA approval of Ascent's reprocessing procedures. The Court assumes, without deciding, that Barkalow is qualified to offer this opinion. Nonetheless, the Court excludes the opinion because it is not relevant to any of Kapps's claims against Ascent. Further, even if the opinion had some limited relevance, the Court would exclude it under Fed. R. Evid. 403.

Whether Ascent's reprocessing procedures damaged the failed catheter is an entirely separate question from whether Ascent sought FDA approval for those procedures through the proper route. That is, even if Ascent had received 510(k) approval for reprocessing Lasso catheters, Ascent could still be liable for selling a defective Lasso catheter if, in reprocessing a particular catheter, Ascent damaged the catheter and rendered it defective. And, conversely, if Ascent did *not* damage a catheter during reprocessing, then even if Ascent should have sought 510(k) approval for its reprocessing procedures, Ascent's failure to seek such approval would not render an undamaged catheter defective.

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[16](...continued)
a physician I expect a LASSO Catheter as used in Dr. Kapps'[s] procedure to be strong enough to withstand such regularly applied force.").

[17]Packer Dep. at 103 ("Q: [Y]ou would expect that the Lasso tip would be designed with enough strength so that it could withstand some manipulation; correct? A: Yes." (objection omitted)).

Further, even if Ascent failed to comply with FDA regulations, Kapps cannot recover from Ascent for this failure alone. Under *Buckman Co. v. Plaintiffs' Legal Committee*, a private litigant may not sue a medical-device manufacturer for violating the FDCA. 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . :"); *see generally Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 775-77 (D. Minn. 2009) (discussing preemption of FDCA-related claims).[18] Yet Kapps's arguments about Ascent's compliance with FDA regulations amount to nothing other than an attempt to hold Ascent liable for violating the FDCA.

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[18]There are two different types of preemption of FDCA-related claims: (1) express preemption under 21 U.S.C. § 360k(a) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and (2) implied preemption under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *See Riley*, 625 F. Supp. 2d at 775-77.

Kapps moved for summary judgment that "preemption doesn't apply" because "the Lasso catheter is at most a 510(k) device," not a Class III device subject to premarket approval. Pl. Mem. Supp. Mot. Exclude & S.J. at 29 [Docket No. 51]. Kapps's motion related only to express preemption, not implied preemption, as demonstrated by Kapps's citation of *Riegel* but not *Buckman*. *See id.* In response, Ascent agreed that *Riegel* did not preempt Kapps's claims but said that *Buckman* did. Ascent Mem. Resp. Pl. Mot. Exclude & S.J. at 26 [Docket No. 88]. Kapps responded by citing *Riegel* and saying nothing about *Buckman*. Pl. Reply Mem. Supp. Mot. Exclude & S.J. at 14 [Docket No. 104].

In the Court's order after the March 17, 2011 hearing, the Court denied Kapps's motion for summary judgment on FDA preemption as moot "because defendants are not raising a preemption defense." Order Mar. 18, 2011 at 5. This order related only to express preemption under *Riegel*, which is the only type of preemption on which Kapps sought summary judgment.

The Court discussed the question of implied preemption under *Buckman* with Kapps at the March 17, 2011 hearing. Hr'g Tr. 80:4–83:23 Mar. 17, 2011 [Docket No. 124]. Nothing in the Court's March 18, 2011 order was intended as a ruling with respect to preemption under *Buckman*.

Kapps argues, in cursory fashion, that Ascent's alleged failure to comply with FDA regulations is "admissible as evidence of negligence per se." Pl. Mem. Opp. Defs. Mots. Exclude Expert Testimony at 28 [Docket No. 92]. But this argument cannot be reconciled with *Buckman*.

Under Minnesota law, negligence per se "is a form of ordinary negligence that results from violation of a statute." *Seim v. Garavalia*, 306 N.W.2d 806, 810 (Minn. 1981); *see also Anderson v. State*, 693 N.W.2d 181, 189 (Minn. 2005) (quoting *Seim*). That is, negligence per se "substitutes a statutory standard of care for the ordinary prudent person standard of care, such that a violation of a statute (or an ordinance or regulation adopted under statutory authority) is conclusive evidence of duty and breach." *Gradjelick v. Hance*, 646 N.W.2d 225, 231 n. 3 (Minn. 2002). In a typical negligence case, the plaintiff seeks to hold the defendant liable because the defendant acted carelessly. In a negligence per se case, the plaintiff seeks to hold the defendant liable because the defendant violated a statute.

And that is why a claim of negligence per se cannot be based on a violation of the FDCA. As this Court explained in *Riley v. Cordis Corp.*, to avoid preemption under *Buckman*, a state-law tort claim must be premised on "the type of conduct that would traditionally give rise to liability under state law — and that would give rise to liability under state law *even if the FDCA had never been enacted*." 625 F. Supp. 2d at 777 (emphasis added). A negligence-per-se claim that is predicated on an alleged violation of the FDCA is, by definition, a claim that would give rise to liability under Minnesota law only because of the FDCA's enactment. Such a claim is preempted under *Buckman*.[19]

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[19] *See also, e.g.*, *Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023, 1028 (D. Kan. 2006) (holding that, under Kansas law, "a violation of the FDCA cannot give rise to a (continued...)

The Court also rejects Kapps's cursory and unclear argument that FDA approval "is relevant to the application of the learned intermediary doctrine since Dr. Kapps'[s] surgeon, Dr. Packer, testified that he would not have used the reprocessed Lasso had [he] known Ascent failed to obtain FDA approval for it." Pl. Mem. Opp. Defs. Mots. Exclude Expert Testimony at 29.

The learned-intermediary doctrine is a *defensive* doctrine, not an *offensive* one. It is raised by makers of drugs or medical devices who are accused of failing to warn about the dangers associated with their products. Under the learned-intermediary doctrine, a maker of drugs or medical devices has a duty to warn only doctors (the learned intermediaries) — and not patients — about the dangers associated with a drug or medical device. *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 n.1 (Minn. 1970) ("The manufacturer has no duty to warn the lay public regarding prescription drugs."); *Mozes v. Medtronic, Inc.*, 14 F. Supp. 2d 1124, 1130 (D. Minn. 1998) (holding that *Mulder* extends to medical devices). Thus, the learned-intermediary doctrine forecloses a patient's failure-to-warn claim if a drug company or medical-device manufacturer provides an adequate warning to the patient's doctor. Further, the learned-intermediary doctrine forecloses a patient's failure-to-warn claim if a doctor (1) was aware of the information that, according to the plaintiff-patient, a defendant drug company or medical-device manufacturer wrongly failed to provide, and (2) would have taken the same action even if the

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[19](...continued)
negligence per se claim"); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) ("Under Florida law. . . Plaintiff cannot use a negligence *per se* claim to create a private cause of action for Defendant's alleged violations of the FDCA.").

defendant had included that information in a warning. *See Cornfeldt v. Tongen*, 262 N.W.2d 684, 698 (Minn. 1977).

As far as the Court can tell, Kapps does not really mean that Ascent's failure to get 510(k) approval is relevant to the learned-intermediary doctrine. Rather, Kapps simply means that Ascent should be liable for failing to warn Packer that Ascent did not get 510(k) approval for reprocessing the Lasso catheter. According to Kapps, Ascent's warning was defective because it did not say something like: "Ascent did not receive 510(k) approval from the FDA for reprocessing the Lasso catheter. Instead, Ascent used the line-extension procedure. In doing so, Ascent violated FDA regulations, and this reprocessed device is therefore not actually FDA-approved."

There are at least a couple of problems with Kapps's failure-to-warn claim — if, indeed, Kapps is making this failure-to-warn claim (again, Kapps's briefs are far from clear):

First, Kapps's failure-to-warn claim is not viable under Minnesota law. A manufacturer does not have a duty to communicate any and all information that might affect a customer's decision to use one of its products. For example, a manufacturer does not have to communicate that the product was made with child labor or that the manufacturer's president has been convicted of fraud, even though such "warnings" might induce customers not to use the product. The duty to warn is much narrower. In Minnesota, "[t]he duty to warn has been described as two duties: (1) The duty to give adequate instructions for safe use; and (2) the duty to warn of dangers inherent in improper usage." *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 787 (Minn. 1977). Ascent's alleged failure to warn that its reprocessing techniques had not been approved by the FDA breached neither of these duties.

Second, even if Kapps's failure-to-warn claim were viable under Minnesota law, it would be foreclosed by *Buckman*. Kapps's argument (as the Court understands it) is that, *regardless* of whether the reprocessed Lasso catheter was defective and unreasonably dangerous after Ascent's reprocessing, Ascent should have warned Packer that the catheter was not really FDA-approved. But if the catheter *was* defective and unreasonably dangerous after reprocessing, then Kapps has a claim against Ascent for strict liability or negligence. His failure-to-warn claim would be superfluous.[20] At the same time, if the catheter was *not* defective or unreasonably dangerous after reprocessing, then Kapps does not have a state-law claim against Ascent for strict liability or negligence. To allow Kapps to recover on a failure-to-warn claim if the catheter was not in fact defective or unreasonably dangerous would amount to creating a cause of action for a violation of the FDCA. Such a cause of action is preempted under *Buckman*.

[20]Because the claim would be superfluous, the Court would exclude any evidence related to the claim under Fed. R. Evid. 403. Needless to say, the parties could not litigate a claim that Ascent failed to *warn* of violating the FDCA without litigating the question of whether Ascent *violated* the FDCA. This would require the jury to hear extremely lengthy and complex evidence about such topics as the FDCA, FDA regulations promulgated under the FDCA, the FDA-approval process, the classification of medical devices, the 510(k) process, the PMA process, the 510(k) application filed by Ascent in August 2001, the 68 mapping catheters that were the subject of that application, Ascent's decision to use the line-extension procedure with respect to the Lasso catheter in December 2002, and the appropriateness of that decision in light of the differences between the Lasso catheter, on the one hand, and the 68 mapping catheters (particularly the Halo catheter), on the other hand. And the jury would then have to be instructed that Ascent could not be held liable for *violating* the FDCA, but only for failing to *warn* that it had violated the FDCA. The presentation of this evidence would waste the time of the jury (because the only claim to which it would be relevant would be superfluous), the probative value of this evidence would be low (for the same reason), and the danger that such evidence would confuse the jury and unfairly prejudice Ascent would be high.

C. Claims Against Biosense

1. Manufacturing Defect

Without Barkalow's testimony, Kapps has no evidence that Biosense manufactured a defective catheter. The Court therefore grants summary judgment to Biosense on Kapps's strict-liability claim.

Further, even if the Court permitted Barkalow to testify in support of a manufacturing-defect claim against Biosense, his testimony would not support a jury verdict against Biosense. Barkalow's testimony, construed in Kapps's favor, is that (1) the glue joint in the broken catheter failed, (2) a smear of polyurethane glue ended up on the outside of the broken catheter where no glue should have been, ergo (3) the glue joint must have been defectively weak from the time that Biosense made the catheter. These first two assertions are basically uncontested, but the third assertion does not follow from them.

As noted, Barkalow did not explain how the glue smear related to the glue joint's alleged weakness. Barkalow's testimony about the glue smear is analogous to testimony that the Minnesota Court of Appeals found insufficient to support a jury's verdict on a manufacturing-defect claim in *Western Surety and Casualty Co. v. General Electric Co.*, 433 N.W.2d 444 (Minn. Ct. App. 1988).

In *Western Surety*, a headlight made by General Electric Co. ("GE") exploded and injured a car owner. The injured man's insurer, Western Surety, offered expert testimony at trial that the headlight included "a bubble in the seal, a sag and a cluster of bubbles in the seal, and red particles throughout the light," although these things "were not in the headlight's area of failure." *Id.* at 446. The expert labeled these things "anomalies" and said that "they could have been the

origin [of failure] in a different headlight under different circumstances." *Id.* The trial court directed a verdict in GE's favor because the various "anomalies" were not identified by Western Surety's expert as "defects that resulted in the break" — that is, Western Surety "had not established any *causal connection* between the anomalies and the break." *Id.* at 447 (emphasis added).

Likewise, Barkalow's testimony does not establish any *causal connection* between the glue smear on the outside of the failed catheter and the failure of the glue joint between the lasso portion of the catheter and the catheter body. For all Barkalow knows — and for all a jury could know based on his testimony — the glue smear could have been a purely cosmetic defect with no relation to the strength of the glue joint. Nothing but speculation connects the glue smear on the outside of the catheter to the failure of the glue joint on the inside of the catheter, and speculation is insufficient to support a jury verdict against Biosense on a manufacturing-defect claim.

Moreover, Kapps cannot rely on the doctrine of res ipsa loquitur to support his manufacturing-defect claim against Biosense. To establish the existence of a manufacturing defect using res ipsa loquitur, a plaintiff must show (among other things) that the allegedly defective product did not undergo any significant changes after it was manufactured. *See Western Surety*, 433 N.W.2d at 449 ("[W]here lapse of time and substantial opportunity for mishandling of a product by third parties make it equally probable a defective condition developed after leaving the defendant's control, neither the principles of res ipsa loquitur nor strict liability will support a finding of liability."). Before it broke in Kapps's heart, the catheter at issue in this case was both (1) used in another patient and then (2) reprocessed by Ascent — both of which presented substantial opportunities for the condition of the catheter to be changed

in a material way. Kapps therefore cannot show that, when the catheter was used in his procedure, it was in the same condition as it had been when it left the control of Biosense. Indeed, Kapps has made no effort to show that the condition of the catheter was unchanged — because obviously that would be inconsistent with the thrust of his case, which is that the catheter was significantly degraded when it was reprocessed by Ascent.

2. Warning Defect

Kapps's warning-defect expert, Benditt, opined that the Lasso was defective for two reasons: (1) it lacked adequate warnings about the risk of mitral-valve entrapment, and (2) it lacked adequate instructions about how to extricate an entrapped Lasso. Benditt Rept. at 4. Kapps also argues, in response to Biosense's summary-judgment motion, that the Lasso was defective because Biosense did not warn of the dangers associated with reprocessing. Pl. Mem. Opp. Biosense Mot. S.J. at 19 [Docket No. 98]. Kapps cannot prevail on either theory. The Court first addresses Benditt's testimony about entrapment and extrication, and then turns to Kapps's argument about the dangers of reprocessing.

a. Risk of Entrapment and Methods of Extrication

To prevail on a warning-defect claim under Minnesota law, a plaintiff must establish three things: (1) the defendant had a duty to warn; (2) the defendant breached that duty by providing an inadequate warning (or no warning at all); and (3) the defendant's inadequate (or nonexistent) warning caused the plaintiff's damages. *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987); *see also Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004).

The first element — the existence of a duty to warn — is a question of law for the court; the remaining two elements are questions of fact for the jury. *Balder*, 399 N.W.2d at 81. A

defendant has a duty to warn about a hazard "if the consequence [of the hazard] is direct and is the type of occurrence that was or should have been reasonably foreseeable . . . ." *Germann v. F. L. Smithe Mach. Co.*, 395 N.W.2d 922, 924 (Minn. 1986).

Biosense contends that it had no duty to warn about the risk of mitral-valve entrapment or to provide instructions about how to deal with entrapment once it has occurred. But Biosense does not argue that entrapment was not reasonably foreseeable. Instead, Biosense argues that it was not the Lasso's manufacturer and thus had no duty to warn. Biosense Mem. Supp. Mot. S.J. at 22-25 [Docket No. 77].

Ascent usurped one of Biosense's functions as a manufacturer — the function of providing instructions to customers — when Ascent replaced Biosense's instructions for use with Ascent's own. Thus, if Kapps's claim depended on an argument that Biosense negligently failed to include certain warnings in its instructions for use, Kapps's warning-defect claim against Biosense would fail for lack of causation: Kapps's damages could not have been caused by the omission of a warning from *Biosense's* instructions for use, because Ascent replaced Biosense's instructions with its own, and thus Biosense's instructions did not accompany the catheter that injured Kapps. *See Balder*, 399 N.W.2d at 81 (causation is an element of a warning-defect claim).

But Kapps's warning-defect claim is not based on Biosense's instructions for use. Indeed, Benditt admitted that "doctors don't read [instructions for use] in great detail every time." Benditt Dep. at 85. Benditt therefore opined that Biosense should have warned about the risk of mitral-valve entrapment in a "Dear Doctor" letter — a supplemental letter to all doctors who use Lasso catheters. *Id.* at 115. According to Benditt, "[t]he letter would say, Dear Doctor,

we have had a few reports of entrapment of this catheter in the mitral valve. Please be very careful with its use in the atrium, et cetera, et cetera." *Id.* at 105.

Setting aside for the moment whether such a "Dear Doctor" letter was permissible under federal regulations, the Court rejects Biosense's argument that because Ascent reprocessed the Lasso catheter, Biosense was no longer the catheter's manufacturer and thus had no duty to warn. In making this argument, Biosense relies almost exclusively on cases in which courts rejected failure-to-warn claims against makers of name-brand drugs brought by users of generic equivalents. Biosense Mem. Supp. Mot. S.J. at 23-24 (discussing *Mensing v. Wyeth, Inc.*, No. 07-3919, 2008 WL 4724286, 2008 U.S. Dist. LEXIS 89365 (D. Minn. Oct. 30, 2008) and *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001)). But generic drugs are manufactured *only* by the generic-drug manufacturer, not by the name-brand-drug manufacturer. Lasso catheters were manufactured in the first instance by Biosense, not Ascent. The fact that Ascent, in reprocessing the catheters, *also* became a manufacturer in some respects does not change the fact that Biosense was the catheters' *original* manufacturer and sold the catheters to doctors. The Court therefore finds — at least for the sake of argument — that Biosense had a duty to warn doctors of the risk of mitral-valve entrapment.

Whether Kapps could show that Biosense should have made the warning in a "Dear Doctor" letter (as opposed to in the catheter's instructions for use) is a harder question. When a defense attorney asked Benditt whether "any regulatory requirements are imposed upon a device manufacturer for sending out 'Dear Doctor' letters," Benditt replied:

> I don't know them. I'm assuming that there must be some, because the implantable device manufacturers seem to send out letters fairly frequently. So there are probably some, but I can't quote them.

Benditt Dep. at 91-92. Given Benditt's acknowledgment that regulations likely govern the sending of "Dear Doctor" letters, it seems reasonable to expect Kapps to show that Biosense could have sent out the type of "Dear Doctor" letter that Kapps calls for without violating those regulations. But neither party has discussed the regulations covering "Dear Doctor" letters. The Court therefore will assume, for the sake of argument, that Biosense could have issued the warning advocated by Kapps. The Court will also assume, again for the sake of argument, that Wong and Packer would have paid closer attention to a "Dear Doctor" letter than to instructions that accompanied the catheter.

Nonetheless, Kapps's warning-defect claim must be dismissed because he cannot show that his injuries resulted from Biosense's failure to provide the warnings that Kapps calls for. Specifically, Kapps cannot show that either Packer or Wong would have done anything differently if Biosense had sent out the "Dear Doctor" letter proposed by Benditt.

To begin with, the warnings proposed by Benditt are virtually content-free. With respect to the risk of mitral-valve entrapment, Benditt proposed telling doctors in a "Dear Doctor" letter to "be very careful" when using the Lasso catheter because "we have had a few reports of entrapment of this catheter in the mitral valve." Benditt Dep. at 105; *id.* at 106 ("Q: So what you're saying is that doctors should be told that there's a risk of entrapment, and they should be careful? A: That's all we need."). With respect to instructions for extricating an entrapped Lasso catheter, Benditt did not propose any particular warning. At one point in his deposition, he said that "one of the instructions *might* simply have been, if you get this thing entangled and it doesn't disentangle with a little clockwise torque, you would call a surgeon." *Id.* at 115 (emphasis added). But soon after Benditt said this, he and a defense attorney had this exchange:

> Q: So what you're telling us is that you are going to provide the opinion that there should have been something as to how to disentangle, but you are not going to render the opinion as to what should have been included. Is that right?
>
> A: That is absolutely correct.

Benditt Dep. at 117-18.

Even without the testimony of Wong or Packer, the Court does not believe that a jury could find that the Lasso catheter was defective because it lacked the warnings that Benditt proposes. Under Minnesota law, if a plaintiff's proposed warning would not have changed anyone's behavior, a product cannot be defective for lacking that warning.[21] Would a doctor who is manipulating a catheter inside a patient's heart near the mitral valve become more careful if he read a warning saying, "Be careful not to get this catheter trapped in the mitral valve"? Surely doctors know, based both on their training and on common sense, that they must be "very careful" when manipulating an instrument inside a human heart. And if the tip of a Lasso catheter became entrapped in a patient's mitral valve, how would a doctor's behavior change if he read a warning from Biosense that said, in effect, "Do something — we're not saying what, but something — to extricate the catheter's tip from the mitral valve"? It's not as if the doctor, without the warning, would leave the tip behind.

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[21] *See Balder*, 399 N.W.2d at 82 (upholding verdict for defendant on failure-to-warn claim where there was "no reason to believe that a warning label would have done anything more to impress" the injured plaintiffs); *Hauenstein v. Loctite Corp.*, 347 N.W.2d 272, 276 (Minn. 1984) ("If the jury . . . concluded that [the injured plaintiff] would not have acted differently even if there was a warning, they were correct in concluding that [the defendant's] negligent failure to warn was not the cause of [the plaintiff's] injury."); *Krein v. Raudabough*, 406 N.W.2d 315, 320 (Minn. Ct. App. 1987) (lack of evidence that absence of warning caused plaintiff's injuries precludes claim for failure to warn).

Further, Kapps did not depose Wong, who was manipulating the catheter when it became entrapped in Kapps's mitral valve. Kapps thus has no evidence that a "Dear Doctor" letter warning Wong to be careful about mitral-valve entrapment would have prevented the Lasso's entrapment and Kapps's subsequent injuries. There is not a shred of evidence in the record that, had Wong been warned that he should be careful about mitral-valve entrapment, he would have done anything differently.[22]

Kapps did, however, depose Packer, who supervised Wong and who was in charge of extricating the catheter once it became entrapped. And Packer testified that in the time since

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[22]The Court notes that some states apply a so-called "heeding presumption" in failure-to-warn cases — that is, a rebuttable presumption that warnings will be heeded. *See generally Tuttle*, 377 F.3d at 925 n.5 ("In products liability law, a majority of jurisdictions recognize a rebuttable presumption that if a product comes with a warning, the user will read and heed the warning."). But the heeding presumption does not help Kapps, for two reasons:

First, the Minnesota Supreme Court has not adopted the heeding presumption. *See id.* at 925 ("[T]he Minnesota state courts have not adopted the so-called 'heeding presumption' within the context of a failure to warn claim."); *Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 99-100 (Minn. 1987) (sustaining verdict for plaintiff on failure-to-warn claim "[w]ithout deciding whether a rebuttable presumption exists that a warning would have been heeded").

Second, even if the Minnesota Supreme Court had adopted the heeding presumption, it would not help Kapps in this case. What is presumed under the heeding presumption is that the omitted warning would have been heeded, not that the heeding of the omitted warning would have prevented the plaintiff's injury. Suppose, for example, that a plaintiff argues that the manufacturer should have warned that its product should be used only in a well-ventilated area. Suppose further that the plaintiff was using the product in a well-ventilated area when he was injured. The heeding presumption would do the plaintiff little good. All that would be presumed is that, had the plaintiff received the warning, he would have used the product in a well-ventilated area. But the plaintiff *did* use the product in a well-ventilated area. Thus, the absence of the warning could not possibly have caused the plaintiff's injury.

So it is in this case. Again, Biosense is being faulted for not warning Wong to "be very careful" in manipulating the Lasso catheter inside Kapps's heart. But there is no reason to believe that Wong was *not* being very careful. Put differently, there is no evidence that, if Wong had heeded the warning to be very careful, he would have done something differently — and thus there is no evidence that the absence of that warning caused Kapps's injuries.

Kapps's procedure, Packer has not changed anything about how he uses Lasso catheters (apart from briefly stopping his use of *reprocessed* Lasso catheters).[23] But Kapps's procedure gave Packer direct personal knowledge of the very information that Kapps says Biosense should have included in its "Dear Doctor" letter. Packer learned from Kapps's procedure (if he did not already know) that Lasso catheters can become entrapped in a patient's mitral valve, and that an

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[23]Packer and Ascent's attorney had the following exchange:

> Q: . . . [F]ollowing the incident with Dr. Kapps, you have not switched . . . the type of catheters that you use in performing this procedure?
>
> A: Yes.
>
> Q: What have you done?
>
> A: I continued to do the same approach that we had done, with the same catheters.
>
> . . .
>
> Q: . . . So have you made any changes in how you perform this procedure today from how it was performed with Dr. Kapps?
>
> A: We've continued to use the Lasso. We continue to use extreme caution. We continue to, you know, do the best that we can with this.
>
> Q: So the answer to my question as to whether you've made any changes on how you approach this?
>
> A: I have made one transient change.
>
> Q: When was that?
>
> A: When I learned of this . . . proceeding, I stopped using reused catheters for a period of three or four months.

Packer Dep. at 64-65.

entrapped catheter must somehow be removed. With that knowledge, Packer has not changed his behavior *after* Kapps's procedure. It follows that Packer's receipt of that knowledge *before* Kapps's procedure — in the form of a "Dear Doctor" letter from Biosense — would not have changed Packer's behavior *during* Kapps's procedure. Thus, a reasonable jury could not find a causal connection between the warning defect alleged by Kapps and Kapps's injuries.

b. Reprocessing Dangers

In opposing Biosense's summary-judgment motion, Kapps argues that Biosense should have warned doctors that reprocessed Biosense catheters are dangerous. Pl. Mem. Opp. Biosense Mot. S.J. at 19. Kapps has no expert testimony to support this argument. Kapps explains this lack by saying that he did not learn until after the close of discovery about a Biosense study showing that Biosense's catheters become dangerous after reprocessing. *Id.* at 19 n.12.

The Court rejects this argument. There is no dispute that Biosense does not reprocess its own catheters. There is also no dispute that Biosense labels its catheters for single use only and thereby communicates to users that they should *not* reprocess the catheters. In light of those facts, it is fanciful to suggest that Biosense has a further duty to tell doctors, in effect:

> Our catheters are labeled for a single use. We really mean it. Some companies will offer to reprocess our catheters. Those companies will tell you that the reprocessed catheters are safe. Don't believe them.

Even if it is true that reprocessing renders Biosense catheters unsafe, the Court finds, as a matter of law, that in light of the fact that Biosense warned doctors not to use reprocessed catheters *at all*, Biosense had no duty to emphasize that it was serious about its warning or to elaborate on the reasons for its warning. *See Balder*, 399 N.W.2d at 81 (existence of a duty to warn is a legal question).

3. Design Defect

Biosense contends that Kapps has no evidence to support a claim that the Lasso catheter was defectively designed. The Court agrees and grants summary judgment to Biosense on Kapps's design-defect claim.

In its summary-judgment memorandum, Biosense addressed Kapps's design-defect claim in a footnote, saying that Kapps "is apparently no longer pursuing his design defect claims as he has offered no expert testimony to support them." Biosense Mem. Supp. Mot. S.J. at 2 n.1. In response, Kapps asserted — erroneously — that his "claims for design defect have been left unrebutted and unchallenged." Pl. Mem. Opp. Biosense Mot. S.J. at 23 [Docket No. 98].

At the hearing on the parties' cross-motions, Kapps responded for the first time to Biosense's argument that Kapps lacked expert testimony to support a design-defect claim. Kapps argued that Benditt was retained to offer, and did offer, an opinion regarding design defect (as well as an opinion regarding warning defect). Hr'g Tr. Mar. 17, 2011 at 188 ("The intent was [Benditt's opinion] was design defect and failure to warn.").

The Court has reviewed both Benditt's report and his deposition testimony. To begin with, the Court agrees with Biosense that it was not put on notice that Benditt would be offered as an expert to support Kapps's design-defect claim. The Court therefore excludes Benditt's testimony about a design defect under Fed. R. Civ. P. 37(c)(1) for Kapps's failure to comply with Fed. R. Civ. P. 26(a)(2) and with the Court's third amended pretrial scheduling order as it relates to expert discovery. Order Sept. 28, 2010 [Docket No. 33].

Further, Benditt's deposition testimony directly contradicts Kapps's contention that Benditt was retained to offer an opinion with respect to a design defect. Benditt and a defendant's attorney had the following exchange at his deposition:

> Q: . . . Are you going to offer an opinion as to an alternative design with respect to this catheter?
>
> A: I could if somebody asked me about it.
>
> Q: Have you been asked to do that here?
>
> A: No, I haven't been asked to do that.
>
> . . .
>
> Q: And you are not here to offer an opinion as to how the catheter should be designed differently in order to create a reliable way to untangle the catheter in every instance. Is that correct?
>
> A: That is correct.
>
> Q: Okay. Your opinion is limited to the warning that you think should accompany the catheter relative to the extrication of the catheter in an entrapment situation?
>
> A: No. I wouldn't limit myself that much. I think that's part of it, the warning that should be offered when companies observe things. If somebody asked me how would you design this catheter to avoid this problem, if they ask that question, I should feel that I'm free to say this is what I would have done under the circumstance.
>
> Q: Well, have you been asked to do that?
>
> A: No, I haven't been asked to do that.
>
> Q: And are you going to be offering opinions at the trial in this matter as to how the catheter should have been designed in order to avoid . . . the entrapment or the ability to reliably each time remove the catheter?

A: No. My intention is only to point out what the defect is and the failure to warn. I'm not there to offer anybody a brand new idea on how to redesign their catheter.

Q: . . . [W]hat is it specifically about this catheter that is the defect to which you refer here?

A: The defect is the inability to be able to extricate it once it's trapped.

. . .

Q: And is it your opinion that there is a specific design that would allow a reproducible ability to extricate the catheter?

A: Yes. I think there are several options.

Q: And are you going to be testifying as to what those options are?

A: That's not my intention. But if you ask me at trial, I'd give you some ideas.

. . .

Q: Have you engaged in any design efforts . . . to design a circular mapping catheter in a way different than it exists today in order to avoid the defect to which you refer?

A: Not in any organized fashion. I have mentally considered designs but have not written them down, nor have I applied for any intellectual property protection for such designs.

Q: And in the past, have you been involved in any kind of design efforts with respect to circular catheters in general?

A: No, not really.

Benditt. Dep. at 58-62 (objection omitted).

No reasonable person reading this testimony would think that Kapps was relying on Benditt to support a design-defect claim. It is true that Benditt identified a defect, but he said that he would testify about "what the defect is *and the failure to warn*" and would *not* testify

about possible alternative designs. Indeed, Benditt is almost certainly not *qualified* to testify about alternative designs, given that (1) he has never been involved in the design of a circular mapping catheter, and (2) he did not consider alternative designs "in any organized fashion." In any event, by repeatedly stating that he had never been asked to, and did not plan to, testify about an alternative design — and by linking his testimony about a design defect to his testimony about failure to warn — Benditt communicated very clearly that he was going to testify only in support of Kapps's failure-to-warn claim, and not in support of a design-defect claim.

Moreover, even if the Court permitted Benditt to testify that the Lasso catheter was defectively designed, his testimony is not sufficient to support a reasonable jury's verdict on Kapps's defective-design claim. The test for a defective-design claim is a "reasonable-care balancing test . . . ." *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 621 (Minn. 1984). Specifically, whether a product's design is defective and unreasonably dangerous must be determined by "a balancing of the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm." *Id.* (internal quotations omitted).

Benditt offered no testimony on the nature — let alone the burden — of "the precaution which would be effective to avoid the harm" of the Lasso catheter's allegedly defective design. In a defective-design case, the "precaution" that must be weighed in the balance against the harms of a defective design is typically a proposed alternative design. But Benditt admitted to merely speculating about alternative designs and disclaimed any intention to "offer anybody a brand new idea on how to redesign their catheter." Benditt Dep. at 60. Without evidence of a proposed alternative design, a jury cannot possibly engage in the "reasonable-care balancing test" called for by Minnesota law.

It is true that in *Kallio v. Ford Motor Co.*, the Minnesota Supreme Court said that in design-defect cases, "[a]lthough normally evidence of a safer alternative design will be presented initially by the plaintiff, it is not necessarily required in all cases." 407 N.W.2d 92, 96-97 (Minn. 1987). But in a footnote to this very sentence, *Kallio* said: "Conceivably, rare cases may exist where the product may be judged unreasonably dangerous because it should be removed from the market rather than be redesigned." *Id.* at 97 n.8. Moreover, *Kallio* endorsed a jury instruction for design-defect cases that embodies the same type of reasonable-care balancing test called for in *Bilotta*, a case that *Kallio* cited with approval. *Id.* at 96 n.7 ("'The reasonable care to be exercised by a manufacturer when designing a product will depend on all the facts and circumstances, including, among others, the likelihood and seriousness of harm against the feasibility and burden of any precautions which would be effective to avoid the harm.'" (quoting 4 Minn. Dist. Judges Ass'n, *Minn. Practice, Jury Instruction Guides — Civil*, JIG 117 (3d ed. 1986))); *id.* at 96 (citing *Bilotta*).

Properly understood, then, *Kallio* does not dispense with the requirement of an alternative design in design-defect cases. Rather, *Kallio* simply explains that in conducting the reasonable-care balancing test that applies in *all* design-defect cases, the relative costs and benefits of an allegedly defective design must be weighed against the relative costs and benefits of one of two different things: either (1) a proposed alternative design, or (2) the removal of the challenged product from the market. But a plaintiff cannot prevail in a design-defect case simply by arguing, in the abstract, that a product is defectively designed. Instead, the plaintiff must explain why, under the reasonable-care balancing test, the world would be a better place if the product were either designed differently or taken off the market. Because Kapps has no evidence to show that,

taking into account the costs and benefits of the Lasso catheter as currently designed, the catheter should have been designed differently or taken off of the market, Biosense is entitled to summary judgment on Kapps's design-defect claim.

4. Breach of Warranty

Without Barkalow's testimony, Kapps has no evidence that Biosense manufactured a defective catheter. Kapps therefore cannot show that Biosense breached any warranty — express or implied — with respect to the catheter. *See Minn. Mining & Mfg. Co. v. Nishika Ltd.*, 565 N.W.2d 16, 23 (Minn. 1997) ("[P]laintiffs in breach of warranty cases must prove that there was a warranty, that it was breached, and that a loss was caused by the breach."). The Court therefore grants summary judgment to Biosense on both of Kapps's breach-of-warranty claims.

Further, Biosense is entitled to summary judgment on Kapps's breach-of-implied-warranty claim for an additional reason: Under Minnesota law, "[s]trict liability has effectively preempted implied warranty claims where personal injury is involved." *Nimeth v. Prest Equip. Co.*, No. C1-93-685, 1993 Minn. App. LEXIS 893, at *3, 1993 WL 328767, at *1 (Minn. Ct. App. Aug. 31, 1993); *Cont'l Ins. Co. v. Loctite Corp.*, 352 N.W.2d 460, 463 (Minn. Ct. App. 1984) ("Once strict liability is the broader theory of recovery. . . warranty of fitness has been pre-empted."); *see also Masepohl v. Am. Tobacco Co.*, 974 F. Supp. 1245, 1253 (D. Minn. 1997) (quoting *Nimeth*).

5. "Negligence"

Even if negligence and strict liability are separate theories of liability in a manufacturing-flaw case (which is doubtful), Kapps's negligence claim necessarily fails along with his strict-liability claim. If a reasonable jury could not find that the catheter that injured Kapps was

defective and unreasonably dangerous when it left Biosense's hands — and, as explained above, a reasonable jury could not make that finding, with or without Barkalow's testimony — then a reasonable jury necessarily could not find that Biosense acted negligently in manufacturing the catheter. *See Halvorson v. Am. Hoist & Derrick Co.*, 240 N.W.2d 303, 307 (Minn. 1976) ("[T]he jury's findings of no strict liability but 25-percent negligence are inconsistent and irreconcilable. . . . If a product is not dangerous and defective in the absence of safety devices, it is not negligence to manufacture it that way.").

Having disposed of all of Kapps's claims against Biosense, the Court now turns to Kapps's claims against Ascent.

D. Claims Against Ascent

1. Manufacturing Defect

Ascent makes two different arguments to support summary judgment in its favor on Kapps's manufacturing-defect claims. The first argument is an extension of Ascent's arguments that Barkalow's and Benditt's testimony should be excluded under *Daubert*. According to Ascent, without their expert testimony, *all* of Kapps's claim against Ascent fail because Kapps cannot establish that Ascent caused Kapps's injuries by damaging the Lasso catheter. Ascent Mem. Supp. Mot. S.J. Based on *Daubert* Mots. at 5 [Docket No. 66]. The second argument is that Ascent is neither a manufacturer nor a seller and thus cannot be liable for anything but negligence under Minnesota law. Ascent Mem. Supp. Mot. Partial S.J. at 2 [Docket No. 71]. The Court addresses each argument in turn.

For reasons given above, the Court is excluding only the portion of Barkalow's testimony that relates to whether Ascent properly obtained FDA approval to reprocess the Lasso catheter.

Similarly, for reasons given above and during the March 17, 2011 hearing, the Court is excluding only the portion of Benditt's testimony that relates to FDA approval of the Lasso catheter — which, it should be noted, is the only portion of Benditt's testimony that Ascent *sought* to exclude.[24]

Both Barkalow and Benditt are thus permitted to testify for Kapps on the key element of a manufacturing-defect claim based on the theory of res ipsa loquitur — namely, whether the Lasso catheter that injured Kapps failed under circumstances in which a defect-free device would not have failed. Because Barkalow's and Benditt's admissible testimony could support a finding of liability on res ipsa loquitur, the Court rejects Ascent's *Daubert*-based summary-judgment motion with respect to Kapps's manufacturing-defect claim.

The Court also rejects Ascent's argument that it is not a manufacturer and thus cannot be held liable for anything except negligence. The Court agrees with Ascent on one point: Whether Ascent is a manufacturer under Minnesota law is a different question from whether Ascent is a manufacturer for purposes of FDA regulations. But the Court is not persuaded that in deciding whether Ascent is a "manufacturer" under state law, today's Minnesota Supreme Court would — as Ascent seems to think — narrowly apply *Graff v. Minnesota Flint Rock Co.*, an antique case that defined a manufacturer as "one who by labor, art or skill transforms raw material into some kind of a finished product or article of trade." 179 N.W. 562, 563 (Minn. 1920).

Instead, the Court believes that the Minnesota Supreme Court would look closely at the nature of Ascent's business to determine whether Ascent should be treated as a manufacturer for

[24]*See* Ascent Mem. Supp. Mot. Exclude Benditt at 1 [Docket No. 56] (asking the Court to exclude Benditt's opinions "that Ascent . . . should have obtained 510(k) clearance and that its use of a line extension was a violation of FDA regulations").

purposes of strict-liability law. And several aspects of Ascent's business strongly suggest that it *should* be treated as a manufacturer. First, Ascent removed Biosense's instructions for using the Lasso catheter and substituted its own instructions — instructions that, for no apparent reason, omitted a warning found in Biosense's instructions about contact with alcohol. Second, Ascent removed Biosense's lot number from the catheter, thus preventing subsequent users from learning about the catheter's manufacturing history. Third, Ascent's entire marketing strategy depended on convincing customers that devices reprocessed by Ascent were exactly equivalent to, and perfect substitutes for, devices made by original equipment manufacturers such as Biosense. Fourth (relatedly), Ascent warranted the functionality of the catheter. And finally, Ascent tells doctors that "legally and practically, we are the *manufacturers* of our reprocessed and remanufactured devices." Ascent Healthcare Solutions, Questions & Answers: Ascent Answers Hospital Physicians' Remanufacturing/ Reprocessing Questions, January 2009 at 2, Barton-Varty Jan. 12, 2010 Dep. Ex. 44 at AHS012968 (emphasis added).

Against all of these facts, Ascent emphasizes that according to its instructions for use, the end user of a reprocessed device — in this case, the Mayo Clinic — retains "title" to the device while Ascent reprocesses it. *See* Ascent Mem. Supp. Mot. Partial S.J. at 8 ("[T]he Mayo Clinic retain[ed] title and ownership of the LASSO Catheters while they were being reprocessed."); Ascent Reply Mem. Supp. Mot. Partial S.J. at 6 [Docket No. 107] ("[T]he catheter belonged to the Mayo Clinic."). The Court has no doubt that, for some purposes, the agreement between Ascent and its end users about "title" to a reprocessed device will have some legal effect. But the Court doubts that, under Minnesota law, the legal effect of that agreement can overcome all of the other indications that Ascent should be treated as a manufacturer for purposes of products-

liability law. When Ascent itself has proclaimed to the world that "legally" it is the "manufacturer" of the devices that it reprocesses, Ascent cannot realistically expect this Court to find, as a matter of law, that it is not the manufacturer of the devices that it reprocesses.

For similar reasons, the Court rejects Ascent's argument that, based on the undisputed facts, Ascent is not a "seller" or a "distributor" for purposes of products-liability law. Ascent's entire argument rests on the notion that it provides the "service" of reprocessing rather than the "product" of a catheter. Ascent Mem. Supp. Mot. Partial S.J. at 8 ("[Ascent] does not provide any product to the Mayo Clinic — it only provides a service."). This argument rests, in turn, on the notion that the Mayo Clinic retained "title" to the Lasso catheter at issue in this case.

In the Court's view, Ascent can fairly be said to have provided *both* a service (reprocessing) *and* a product (a usable catheter). Thus, the Court believes that Ascent fits squarely within the following portion of the definition of "one who sells or otherwise distributes" a product found in Restatement (Third) of Torts: Products Liability § 20(b): "those who provide products to others as a means of promoting either the use or consumption of such products or some other commercial activity."[25] In any event, whether Ascent is a "product distributor," on the one hand, or a mere "service provider," on the other, is a question for the jury.

Finally, the Court believes it likely that the Minnesota Supreme Court would apply the state's products-liability law to Ascent, even if in doing so that court had to recognize Ascent as being some sort of a hybrid entity made up of equal parts manufacturer, seller, and service provider. A true service provider — such as a dry cleaner who cleans a men's suit — does not

[25]As noted, the Minnesota Supreme Court cited with apparent approval § 3 of the Restatement (Third) of Torts in *Schafer v. JLC Food Systems, Inc.*, 695 N.W.2d 570, 576 & n.2 (Minn. 2005) (describing previous cases as consistent with § 3).

provide its own instructions for using the suit, does not remove the original manufacturer's labels or other markings from the suit, does not warrant the *functionality* (as opposed to the cleanliness) of the suit, and does not represent to its customer that "legally and practically, we are the manufacturers of [the suit]." Ascent went far beyond providing a service; it both acted like a manufacturer and characterized itself as a manufacturer. Thus it seems likely that the Minnesota Supreme Court would treat Ascent as a manufacturer for purposes of Minnesota's products-liability law.

For all of these reasons, the Court rejects Ascent's argument that, as a matter of law, the nature of Ascent's business forecloses Kapps's products-liability and warranty claims against it.

2. Warning Defect

Benditt — who, again, is Kapps's warning-defect expert — also offered an opinion about whether Ascent should have filed a 510(k) application with respect to the Lasso catheter. Ascent moved to exclude only Benditt's opinion with respect to the 510(k) issue, and did not move to exclude Benditt's opinion about a warning defect. *See* Ascent Mem. Supp. Mot. Exclude Benditt at 1, 8. Thus, even though the Court granted Ascent's motion to exclude Benditt's testimony regarding the 510(k) issue, Benditt may still — at least as an evidentiary matter — offer testimony to support a warning-defect claim against Ascent.

As far as the Court can tell, Ascent seeks summary judgment on Kapps's warning-defect claim on one theory only — namely, Ascent's insistence that it is not a manufacturer or seller. For reasons given above, the Court denies summary judgment on this basis. Whether Ascent is subject to Minnesota's products-liability laws is a question for the jury — or perhaps a question

that will eventually be decided against Ascent as a matter of law. Thus, the Court denies summary judgment to Ascent on Kapps's warning-defect claim.

The Court notes, though, that in challenging Kapps's warning-defect claim, Ascent did not make the argument that Biosense made and that the Court found persuasive — namely, the argument that Kapps cannot establish that his injury was caused by either the failure to warn of the risk of mitral-valve entrapment or the failure to provide instructions about how to extricate an entrapped Lasso. If this case continues to trial and the evidence with respect to causation does not change substantially, the Court would likely direct a verdict for Ascent on Kapps's warning-defect claim based on Kapps's failure to show causation.

3. Breach of Warranty

For reasons already given, the Court rejects Ascent's argument that Ascent is not a manufacturer and therefore cannot be held liable for breach of any express or implied warranty. But the Court does hold, for reasons given above in connection with Biosense, that Kapps's claim for breach of an implied warranty is superseded by his strict-liability claim. *See Masepohl*, 974 F. Supp. at 1253. Kapps's claim against Ascent for breach of express warranty remains in the case, although the Court questions whether there is any reason for Kapps to continue to pursue this claim, given that his strict-liability claim against Ascent also remains in the case.

4. "Negligence"

As noted in connection with Biosense, the Court doubts that negligence and strict liability are separate theories of liability under Minnesota law in a manufacturing-defect case, and they are definitely not separate theories in a warning-defect case. The Court therefore sees no reason

why Kapps would pursue a negligence claim against Ascent separate from Kapps's strict-liability claims.

Nonetheless, as a formal matter, the negligence claim against Ascent remains in the case, except insofar as Kapps argues negligence per se based on alleged violations of the FDCA or FDA regulations. (Any such argument is foreclosed by *Buckman*.) For reasons given above, the Court will not exclude all of Barkalow's testimony, and his admissible testimony — together with the admissible testimony of Benditt — could support a finding that Ascent is liable in strict liability or negligence (or both) on the theory of res ipsa loquitur.

E. Punitive Damages

Under Minnesota law, a plaintiff can recover punitive damages "only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others." Minn. Stat. § 549.20 subdiv. 1(a). And a plaintiff can only *seek* punitive damages if a court finds "prima facie evidence" to support an award of punitive damages. Minn. Stat. § 549.191; *see also Olson v. Snap Prods., Inc.*, 29 F. Supp. 2d 1027, 1033 n.1 (D. Minn. 1998) ("[I]n applying the provisions of Minnesota Statutes Section 549.191, the Court should examine the evidence in support of a punitive damages claim, without considering the evidence submitted in opposition to the claim."). Because the Court finds no prima facie evidence to support a punitive-damages award against Ascent, the Court denies Kapps's motion to amend his complaint to seek punitive damages.

No reasonable jury could find, by clear and convincing evidence, that Ascent acted with "deliberate disregard for the rights or safety of others" as Minn. Stat. § 549.20 requires for an award of punitive damages. To show such "deliberate disregard" by Ascent, Kapps must show

that Ascent "ha[d] knowledge of facts or intentionally disregard[ed] facts that create[d] a high probability of injury to the rights or safety of others" and then acted with either "conscious or intentional disregard" or "indifference" to this high probability of injury. Minn. Stat. § 549.20 subdiv. 1(b). The facts cited by Ascent to support its motion to add a punitive-damages claim do not support such a showing.

The facts that Ascent relies on fall into three groups: (1) facts related to the reprocessing business in general; (2) facts related to Ascent's decision to consider the Lasso a line extension of devices that were the subject of a prior 510(k) application rather than to file a new 510(k) application; and (3) facts related to Ascent's testing, reprocessing, and packaging of the Lasso catheter. Although some of these facts reflect poorly on Ascent, these facts do not show that Ascent acted with deliberate indifference to patient safety.

Kapps seems to object to the reprocessing industry as a whole when he complains that Ascent reprocesses Lasso catheters "even though the original manufacturer explicitly warned that the device was 'for one use only' and was not to be 'reuse[d]'. . . ." Pl. Mem. Supp. Mot. Am. Compl. at 2 [Docket No. 37]. Given that the FDA regulates the medical-device-reprocessing industry and says that "[r]eprocessing and reusing single-use devices (SUDs) can save costs and reduce medical waste,"[26] the fact that Ascent reprocesses catheters that Biosense markets for a single use cannot be a basis for awarding punitive damages.

Likewise, the possibility that Ascent may have improperly used the line-extension procedure rather than obtaining 510(k) approval to reprocess the Lasso cannot support a punitive-

[26]FDA, Device Advice: Comprehensive Regulatory Assistance, Reprocessing of Single-Use Devices, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm (last visited Sept. 20, 2011).

damages award. Whether to use a line extension or file a new 510(k) application can be a close question.[27] Kapps cannot transform this kind of regulatory mistake — even if the Court assumes that Ascent's failure to file a new 510(k) application *was* a mistake — into deliberate disregard of patient safety or rights. It follows that the representations about FDA approval in Ascent's marketing material do not show deliberate disregard of patient safety or rights. For reasons that the Court has explained at length, Kapps's unrelenting emphasis on FDA approval has been a sideshow that has needlessly complicated these proceedings and distracted the parties from the central question in this case: Was the catheter used in Kapps's procedure defective and unreasonably dangerous?

Only a handful of facts cited by Kapps even hint at improper behavior by Ascent. First, the Court agrees with Kapps that Ascent's elimination of Biosense's lot numbers from reprocessed catheters is imprudent. *See* Pl. Mem. Supp. Mot. Am. Compl. at 18-19. Second, the Court is troubled by Ascent's apparent admission that it does not monitor adverse events that occur with products it reprocesses. *See id.* at 19-20. And third, the Court is concerned about Ascent's use of alcohol and alcohol-containing solutions in reprocessing Lasso catheters, notwithstanding Biosense's warning that its catheters should not come into contact with isopropyl alcohol — and, relatedly, about Ascent's omission of Biosense's warning about contact with alcohol from the instructions that Ascent provides with reprocessed Lasso catheters.

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[27] *See* FDA, Device Advice: Comprehensive Regulatory Assistance, How to Market Your Device — Is a new 510(k) required for a modification to the device?, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134575.htm (last visited Sept. 20, 2011) ("It is not FDA's intent that a 510(k) must be submitted for every modification.").

In the Court's view, however, although these facts may suggest that Ascent was incompetent or careless, these facts do not provide clear and convincing evidence that Ascent acted with deliberate indifference to a high probability that its reprocessed catheters would cause injury. *See Olson*, 29 F. Supp. 2d at 1033 n.1. For that reason, the Court denies Kapps's motion to amend his complaint to seek punitive damages from Ascent.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. The motion of defendant Biosense Webster, Inc. to exclude the expert testimony of Bruce H. Barkalow [Docket No. 80] is GRANTED.
2. The motion of defendant Biosense Webster, Inc. for summary judgment [Docket No. 75] is GRANTED. All of plaintiff's claims against defendant Biosense Webster, Inc. are DISMISSED WITH PREJUDICE AND ON THE MERITS.
3. With respect to the motion of defendant Ascent Healthcare Solutions, Inc. to exclude the expert testimony of Bruce H. Barkalow [Docket No. 59]:
    a. The motion is GRANTED IN PART as follows: Barkalow will not be permitted to testify about whether Ascent's reprocessing procedures were properly approved by the FDA. And Barkalow will not be permitted to describe Ascent's reprocessing procedures as "unvalidated" or "nonvalidated" or to otherwise implicitly opine about whether Ascent's reprocessing procedures were properly approved by the FDA.
    b. Otherwise, the motion is DENIED.

4. The motion of defendant Ascent Healthcare Solutions, Inc. for summary judgment based on *Daubert* motions [Docket No. 64] is GRANTED IN PART AND DENIED IN PART as follows:

   a. Kapps's claim for breach of an implied warranty is DISMISSED WITH PREJUDICE AND ON THE MERITS.

   b. Kapps's claim for negligence per se is DISMISSED WITH PREJUDICE AND ON THE MERITS.

   c. Otherwise, the motion is DENIED.

5. The motion of defendant Ascent Healthcare Solutions, Inc. for partial summary judgment on the basis that Ascent is not a manufacturer or seller [Docket No. 69] is DENIED.

6. Plaintiff's motion for leave to amend his complaint to add a punitive-damages claim [Docket No. 35] is DENIED.

Dated: September 27, 2011

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge